

Eurohealth

RESEARCH • DEBATE • POLICY • NEWS

Volume 14 Number 4, 2008

Another piece of the puzzle:

Commission perspectives on
pharmaceutical innovation



Liberalisation of mental
health care in the
Netherlands

Engagement with Russia
in the health sector

Devolution and health
policy in the UK

Spain: mental health reform • Turkey: health care and pharmaceutical policy • Health governance in France
Finland: welfare state meets consumer society • Czech Republic: First steps on path to reform

COMMENTARY

Putting the pieces of the puzzle in place

Implementing health policy can sometimes feel like trying to complete a highly intricate jigsaw. Many jigsaw pieces look similar, but each one can only fit in one unique place in the puzzle. One constant challenge is how to square the need for investment in pharmaceutical innovation and research with the acute need to contain costs during a time of severe financial constraints. Yet at the same time facilitating a positive environment for research can enhance Europe's competitiveness, potentially protecting jobs, by helping the pharmaceutical sector remain dynamic.

We are thus especially delighted to feature two European Commission perspectives on these issues. European Commissioner for Health, Androulla Vassiliou, sets out an encouraging overview of achievements to date, albeit acknowledging that many challenges lie ahead. Georgette Lalis, Director, DG Enterprise and Industry, reflects on three parts of the puzzle posed by pharmaceutical innovation: patient safety; availability, access and affordability of medicines; and transparency in the disclosure of information. Meeting these challenges will now form much of the focus of the so-called 'Pharma Package', adopted by the Commission in December.

Among other contributions we feature an US perspective from Edward Burger and E. Wayne Merry on opportunities for better engagement and collaboration with Russia in the health sector. They firmly put an emphasis on the need not to rush into action but instead to spend more time listening and learning from Russian practitioners and policymakers.

Reforms continue apace across Europe. Yet remarkably, there has been all too little discussion of the natural experiment arising from a decade of health system devolution in the UK. Here Scott Greer gives us an insight into the resultant divergences in policy that have emerged; many have resonance elsewhere. Other articles include one on general health system reform in Turkey, as well as two on recent reforms to the mental health sectors in Spain and the Netherlands. It is to be hoped that all the contributions to this issue of *Eurohealth* can help us to put a few more pieces of the puzzle in place.

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Research and innovation in pharmaceuticals: Covering unmet needs

Androulla Vassiliou

This text is an edited version of a speech given at the Sixth Biennial Health and Pharmaceutical Summit. Innovation and Value in Health and Pharmaceutical Care, held in Athens, Greece on 24 November 2008.

The provision of the highest quality health care is an issue that requires coordination and dialogue between us all, and I would like to provide an overview of the achievements made so far at a European Union (EU) level in the area of research and innovation from a public health perspective.

As you will know, we have to conduct a very delicate balancing act between high quality public health care, maintaining industry competitiveness, and the provision of cost containment policies. The EU believes in some basic common values and principles for health care. Social protection should ensure that all citizens have access to high quality care independent of their ability to pay. Hence, solidarity and the fair distribution of resources are two key principles inherent to health care systems. Yet these principles do not always today translate into universal access to health care. There remain significant unmet health care needs, not only within the EU, but even more dramatically, worldwide.

New technologies could be part of the solution. But if we are not careful, they could also become part of the problem. Yes, they can help improve quality of life, but at the same time they can create an increasingly difficult challenge for health care policy makers, as the issue of affordability inevitably arises when a new innovative product becomes available.

Androulla Vassiliou is European Commissioner for Health, European Commission, Brussels, Belgium.

Threats to public health

Exactly three years ago the World Health Organization (WHO) held a conference to review implementation of the recommendations outlined in its report on *Priority Medicines for Europe and the World*, an initiative of the Dutch Presidency of the EU in 2004. The report identified a list of priority areas in threats to public health, such as HIV/AIDS, pandemic influenza and antimicrobial resistance, which could be the focus of research and development in the field of pharmaceuticals, vaccines and biologicals for Europe and the rest of the world.

I would like to expand on how the report has influenced the actions of the European Commission. One such example is the Innovative Medicines Initiative (IMI). This was launched in early 2008 with the objectives of supporting the faster discovery and development of better medicines for patients, while enhancing Europe's competitiveness by ensuring that its biopharmaceutical sector remains a dynamic high-technology sector.

It is a unique partnership between the European Community, represented by the European Commission, and the European Federation of Pharmaceutical Industries and Associations. It has benefited from tremendous financial input and will manage €2 billion of funds from both industry and the EU's Seventh Research Framework Programme.

One priority area for the EU is pandemic influenza. The threat of an outbreak of pandemic influenza remains a very real concern. In light of the enormous scale and

impact of such an event our responses and preparedness planning needs to be comprehensive and involve all sectors concerned in a coordinated way. This is not an easy task. The European Commission has responded by playing an important role in helping Member States to improve EU-wide coordination of prevention and control measures for influenza and other communicable diseases.

We are also closely working together with the WHO, for example through a number of workshops, to help Member States prepare for an influenza pandemic. Medical interventions will be a key pillar of defence. In respect of the development of new interventions I, of course, call on the industry to be more active. After all, in recent years many developed countries have increased their stockpiling, and considerable earnings have been realised.

The European Commission is also vigorously supporting research and action on pandemic influenza, both via the EU Seventh Framework Programme and the Health Programme. The Seventh Framework Programme is the most significant EU programme on research and innovation. The current programme, with a budget in excess of €50 billion, runs from 2007 to 2013.

In line with the priorities of the WHO report, the EU is also aiming to implement specific strategies to contain antimicrobial resistance. Through the EU Public Health Programme we have funded projects, to increase and enlarge the quality of surveillance, to set up clear methodology for tests

assessing the resistance of microbes, and to follow up the use of antibiotics among the EU population in each Member State.

One of the most recent projects developed is addressing the economic burden of human diseases related to antibiotic resistant strains of bacteria. A taskforce is being set up within my services to gather human, animal and food aspects in order to share best practices and find appropriate control options. My services are also supporting cooperation between the principal concerned agencies: the European Centre for Disease Prevention and Control (ECDC), the European Medicines Agency (EMA) and the European Food Safety Authority (EFSA). A joint ECDC-EMA working group is currently developing an analysis, looking at the extent of antimicrobial resistance and the availability of efficient therapeutic agents during the coming years.

Moving on to more global perspectives, in recent years, the EU has significantly increased its funding for the fight against HIV/AIDS, malaria and tuberculosis. One of the main initiatives in this area is the European Developing Countries Clinical Trial Partnership (EDCTP). The purpose of this initiative is to accelerate the development of new vaccines and drugs for HIV/AIDS, malaria and tuberculosis by supporting clinical trials in Africa in partnership with developing countries. Since 2003, the EDCTP has committed to funding seventy-four projects that include clinical trials, capacity building and support of research networks. The Commission has so far contributed around €200 million to the project, with participating Member States contributing the same amount in co-funding. It is one of the largest programmes on clinical trials in Africa and creates an unprecedented and genuine North/South partnership, concentrated on the real needs of developing countries.

In the area of neglected infectious diseases, the Seventh Framework Programme will build on the significant progress made within previous Framework Programmes that, since 1997, have provided €70 million to fund fifty-five research projects. Such projects so far have covered a range of relatively little-known diseases including, dengue and haemorrhagic fever, buruli ulcer and other infections that predominantly affect children. Under the Framework Programme there will be an increased focus on applying new modern research methods and technologies in

order to develop new medicines against these diseases.

Another vital element is the focus and effort in relation to health systems research. In addition to the research programme, the EU also helps to fund global initiatives and international partnerships such as: the Global Fund to Fight Aids, Tuberculosis and Malaria, the Global Alliance for Vaccine Initiative, the International AIDS Vaccine Initiative and the International Partnership for Microbicides.

Sound regulatory measures

But investment in research and innovation is not sufficient. We also need to ensure that sound regulatory measures are in place to deal with unmet health care needs. The pharmaceutical industry clearly needs to make a return on its investments, not least to finance and secure its long term work in innovation. On the other hand, it is important that public investment leads to clear gains in terms of a decrease in disease burden, health care costs and lost working days.

To address these challenges health care regulators have a responsibility, not only to encourage research and innovation, but also to provide guidance and the tools necessary to help make the best decisions on where to spend public funds. They must also, of course, ensure that new innovative pharmaceuticals and other technologies are integrated effectively into efficient and high quality health systems.

Significant progress in the regulatory framework has been made at EU level to facilitate research and innovation and to address the multiple objectives of public health promotion, rewarding innovation and cost containment. One such example is the regulatory framework on orphan drugs, which has provided solid incentives for the research, development and marketing of medicines for rare diseases. These diseases require specialist expertise for diagnosis and treatment, and by definition it is difficult to provide such expertise everywhere in the EU.

The Commission is therefore now working on an initiative on rare diseases which aims to improve the availability of information about them and to pull together expertise from across the EU so that all patients can access this. Another example is our recent regulation on children's medicine which covers the development and authorisation of medicines for paediatric use. Studies show that

over 50% of children's medicines may not have been tested specifically for children, leaving health care professionals in a difficult position when prescribing such medicines. Therefore, it is important to ensure the highest quality research, so that medicines used for children are specifically authorised for such use, and to ensure the availability of high quality information about these medicines.

A third regulatory initiative relates to patent provisions. The European Commission has been an active member of the WHO Inter-Governmental Working Group which produced a draft Global Strategy and Plan of Action on public health, innovation and intellectual property. The Global Strategy was adopted by the World Health Assembly in May of this year. It aims to give incentives for innovation and access to medicines, as well as to put a focus on needs-driven research and development. By working together with stakeholders, such as representatives of industry and civil society, to implement this Global Strategy, we should help deliver tangible improvements relating to the availability, affordability and access to medicines worldwide. At the same time we can encourage an optimal environment for pharmaceutical innovation.

Measures have also been taken to help health care regulators with their dual objectives of providing better access to health care while at the same time trying to contain public expenditure. Health care regulators and policy makers need to shape new approaches to make the best use of available public funds. Existing products and new technologies should be subject to health technology assessments to make sure that interventions which bring real therapeutic added value for patients are made available.

The EU has therefore taken two initiatives to promote the development of health technology assessments. The first, the European network on Health Technology Assessment (EUnet HTA), has developed generic tools for adapting health technology assessments made by one country for use in other countries. The second, the Pharmaceutical Forum, was set up in 2005 as a three year process to find solutions to public health issues regarding pharmaceuticals, while ensuring industry competitiveness and the sustainability of national health care systems. Since its inception the Pharmaceutical Forum has made a series of recommendations on the establishment of

fair pricing and reimbursement decisions on pharmaceutical products by Member States.

With regard to affordability, I would like to briefly mention the Bremen process launched in the Bremen conference on HIV/AIDS in March 2007. The European Commission is actively supporting Germany in its efforts in this area, as indi-

cated when in 2007 the Commission adopted its EU Health Strategy. One objective of the Bremen process is to help new EU Member States and our direct neighbours to the East, for example Ukraine and Moldova, to tackle their HIV and AIDS problems effectively by helping them to gain access to reduced-price anti-retroviral medicines.

This article provides a snapshot of the many different initiatives the European Commission is working on to deal with the unmet health care needs of today and tomorrow. Naturally, we are keen to make further progress together with key stakeholders, all of whom share the same core objective: to provide the highest quality health care for citizens.

Does fostering pharmaceutical innovation and competitiveness benefit the European patient?

Georgette Lalís

This text is an edited version of a speech given at the Sixth Biennial Health and Pharmaceutical Summit: Innovation and Value in Health and Pharmaceutical Care, held in Athens, Greece on 24 November 2008.

For thousands of years diagnosis and treatment were based on what could be seen, tasted, felt, smelled or based on intuition. Over the course of the last hundred years, diagnosis and treatment have increasingly been based on our growing knowledge of biochemistry and cellular processes. Today diagnosis and treatment are ever more likely to be based on rapidly developing insights into molecular processes and variations in our genes.

Progress in the life sciences, and particularly in biotechnology, has led to the development of new drugs and enabling tools for diagnosis. Additionally, the completion of the human genome project has made it easier to associate specific genes (or gene combinations) with a disease, and thus to identify novel drug targets.

We are facing revolutionary changes. In pharmaceuticals, the medicine of the future

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might well be personalised. It will become possible to produce medicines which have fewer side-effects and/or are more effective because they can be more closely attuned to the genetic disposition of the patient. Many developments might be expected as a result of these changes (see Box) but they also pose at least three challenges: patient safety; the availability, access to and affordability of quality medicines; and transparency of information.

Improving safety

Safety lies at the heart of EU drug legislation since its beginnings in 1965 when, following the Thalidomide disaster, we initiated the first directive. We now have a solid set of legal provisions ranging from clinical trials to manufacturing, market authorisation and post market surveillance, as well as covering orphan drugs, paediatrics, herbal medicines and last but not least advanced therapies.

With regard to pre-marketing safety, the EU's approach has received broad support

Box: Potential future developments

- More convergence in technologies, i.e. more combination products (for example, combination medical device/medicinal substances)
- Advanced diagnostic tests for earlier and more accurate diagnosis
- More emphasis on prevention and a more holistic approach, to chronic disease in particular
- More personalised treatment instead of non-targeted broad-based therapies
- More use of genomics to enable physicians to deliver higher quality, cost-effective care faster to more patients
- More ambulatory surgery to allow patients to return home rapidly
- Less invasive treatment options, with better clinical outcomes and shorter recovery times and a general reduction in the length of hospital stay
- Greater use of home based diagnostics by people with chronic conditions, including high blood pressure, diabetes, asthma and heart problems
- Wider and improved data mining, i.e. in particular, hospital data will become a source of valuable information and improve the conclusions that may be drawn from clinical studies

and is held in high esteem internationally for the rigorous assessment of safety quality and efficacy it provides. The European Medicines Agency has an impressive track record in delivering high-quality assessment and speedy access of innovation to the European market.

Recent events linked to adverse reactions, coupled with the upswing in detected counterfeit medicines, demonstrate that the safety of medicines remains a major public health issue. There is an urgent need to address the potential dangers brought about by the globalisation of the value chain. New markets (for example, China, India, Brazil, Russia, Indonesia, Mexico and Turkey) have become centres for production of Active Pharmaceutical Ingredients (APIs) and prime sources for European imports of those substances. A growing number of medicines are now developed simultaneously in multi-centre studies on different continents. Ingredients and finished products are ever more sourced through international distribution channels. This makes the task of authorities charged with evaluating trials and inspecting sites more difficult and resource-intensive.

The Commission's *Report on Community Customs Activities on Counterfeit and Piracy for 2007* revealed that medicines seized by customs authorities increased by 628% in just two years (2005–2007). This not only affects so-called 'lifestyle' products, but also essential treatments against life-threatening diseases. It is a vivid reminder that action against counterfeiting is urgently needed.

The Commission now intends to submit legislative proposals within its forthcoming Pharmaceuticals Package, in order to rationalise and strengthen the EU framework on safety monitoring (pharmacovigilance), and to address the topic of counterfeit drugs. Various measures are proposed, ranging from product-related measures (such as obligatory safety features and traceability) to strengthened obligations and reporting mechanisms for the whole supply chain including API manufacturers and distributors.

But measures aimed only at the EU market are no longer sufficient. Global industry requires the global cooperation of regulators and global monitoring. As scarce resources have to be used efficiently, intensifying regulatory cooperation with the US, Japan and Canada, both within the International Conference on Harmoni-

sation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) and existing confidentiality arrangements, remain our priority. Our field of cooperation will extend to mutually agreed mechanisms for joint inspections in third countries.

At the same time, we are intensifying bilateral cooperation with targeted third countries that are important trade partners. New mechanisms for the exchange of information on illegal distribution channels and counterfeiting, as well as on clinical trials and the manufacturing of APIs, are being established with Russia, India and China.

Availability, access and affordability

These three issues are of extreme importance if we want the innovative drugs that our societies need to be available and accessible to EU patients at an affordable price. Turning first to the supply of drugs, there is an ongoing debate in the World Health Organization (WHO) and other international fora on what are the priority drugs for combating diseases across the world. This gives rise to the question of whether the concept of priority drugs is relevant and valid and, if so, whether decisions should be left to industry alone.

We see more and more private organisations interfering in defining the needs of less developed countries. Should we not also engage in a wider discussion between policy makers, industry and patients on the drugs that our ageing societies need? We know already, for example, that the pipeline is full for oncology, much less so for neurological diseases and, most worryingly, almost empty for antimicrobial resistance. On a more general level, is the present business model, dominated by the 'one fits for all' approach – the blockbuster model, still valid?

But this is only one part of the question. The other part is whether Member States' public health budgets are capable of coping with such innovative drugs? The sustainability in financing of an ever more modern (and probably more costly) health care sector is a concern which requires our undivided attention.

Socially less favourable ramifications might also materialise, namely signs of a two-tiered polarised health care system. Health insurance systems might be forced into no longer paying for everything, and those who can purchase their services in the private for-profit market will do so,

thus creating socioeconomic inequalities and a health divide between the rich and poor, young and old. The concept of solidarity and the European social model might come under increased stress if measures are not taken early enough.

To make future innovative drugs accessible to the patients of Europe, we need to ensure that:

(1) *Development and marketing costs must be brought down by industry.* Attrition rates are too high. Fewer substances overcome the costly and time-consuming pre-market authorisation requirements. We hear more and more about the benefits of personalised drugs and therapies. It is fair to say that such drugs will be extremely efficient, thus saving both the lives of patients and money to health care payers. However, with the existing development models and rate of attrition, we also know that they will necessarily be more costly, as a smaller number of industry actors will bear their developments costs. At the EU level, industry and the Commission have created a partnership, the Innovative Medicines Initiative, in order to foster research into new pathways for the development of innovative drugs. We place our hopes in biomarkers to reduce both costs and the rate of failure. When this research produces results, we will consequently be able to update the regulatory framework.

Equally, too much money is spent by industry on marketing rather than research. This is part of the business model that has to be reviewed because it has reached the limits of its sustainability. Not only are payers less and less ready to pay for such costs, but it also tarnishes the industry's image.

(2) *Regulators, policy makers and payers have to review their pricing and reimbursement systems to reward innovation and promote the use of generics and over the counter products.* The EU has a single market, albeit not perfect, for market authorisation but a fragmented market as far as pricing and reimbursement are concerned. The combined effects of different national systems through parallel trade is detrimental to both industry and patients. Public health budgets should not operate as silos where pharmaceutical expenditures are determined in isolation. The global benefits that a drug creates should be taken into account when deciding on reimbursement. The design of intelligent cost-containment measures is of

paramount importance to the future.

The promotion of generics is also of paramount importance if we want to create headroom to reward innovation, while making expensive drugs broadly available to patients. The European Commission launched a sector enquiry to examine the relationship between originators and generics, and more specifically the ways intellectual property rights and agreements between companies influence the entry of generics into the market. Indeed, the EU Commissioner for competition presented the first results of this inquiry on 28 November 2008.

(3) Finally, and I realise that this point is debatable, we might have to *engage in a societal debate on the notion of risk-benefit*. No drug is safe and the samples we have from phase III clinical trials are not enough to ensure the best possible risk-benefit assessment. At the same time, our society seems to have become increasingly risk-averse, while at the same time patients affected by a disease expect new drugs to be available on the market as soon as possible. It is clear that increasing safety via regulatory requirements increases costs. Should we make a wider use of risk management plans and phase IV studies combined with a robust pharmacovigilance system? The debate is open.

There are, however, two other important aspects concerning the availability of innovative drugs.

One is the fact that some Member States that represent small markets for pharmaceuticals experience shortages in drugs, especially for products of low volume, low price or those intended to treat severe and/or rare diseases. Let us not hide the facts: Cyprus and Malta are most severely affected but other Member States encounter the same problems.

This is an unacceptable situation that we cannot tolerate within the EU. Over the past few years we have had intensive discussions on the issue. We started by first trying to understand the contributing factors and then subsequently developing solutions within the relevant network of the Heads of Medicines' Agencies, and finally, within the Pharmaceutical Forum.

A series of recommendations were formulated, some of which have to be taken to the regulatory level, for example by simplifying the Mutual Recognition Procedures to allow Member States who wish to do so to rely completely on an agency in another

Member State, or by waiving the language barrier. Another idea discussed was whether those drugs considered within the centralised procedure should not be placed on the markets of all Member States, if the market authorisation holder wants to benefit from the advantages linked to centralised market authorisation. Other solutions, notably those linked to economic aspects of the supply of drugs in these Member States, have yet to be tackled. I refer here to the way the wholesaling of drugs is organised, the way public procurement is designed, and finally pricing and reimbursement regimes. This is certainly an issue that will stay on our agenda, especially our regulatory agenda, for years to come.

The second issue is the impossibility of some Member States to reimburse critical medicines, in particular due to a lack of adequate financial resources. This issue has reached the highest political levels, as exemplified by the 'Bremen Declaration' in the case of HIV/AIDS, where health ministers invited industry to commit to cooperating in order to ensure access to affordable medication for patients in several new Member States. For instance, those Member States, and their patients, saw the price of HIV medication dramatically increase following their accession to the EU (this is a collateral effect of parallel trade that is seldom discussed).

For issues related to pricing and reimbursement the Pharmaceutical Forum has proven an interesting experience. A common set of guiding principles has been adopted by that Forum to support future national pricing and reimbursement policies. The positive experience of information exchange and cooperation between Member States and with stakeholders should be strengthened at EU level. More efficient market mechanisms and, in particular, price competition for non-reimbursed medicines, would provide, in this sector, more patient choice at a more affordable cost. Recommendation six of the G10 group was again endorsed by the Forum. It stipulates that Member States should remove price controls on manufacturers that prevent full competition in authorised medicines that are neither purchased nor reimbursed by the State.

Further developments in health technology assessment will also offer valuable support to national authorities in striking a balance between containing pharmaceutical expenditure and ensuring a fair reward for valuable innovation and access

to the best available medicines. Cooperation among authorities and dialogue with stakeholders will be a prerequisite to achieving such a balance.

The results of the Pharmaceutical Forum show what can be achieved through dialogue and cooperation among stakeholders. We will be able to progress only through close co-operation, i.e. a genuine partnership between the Commission, the Member States, industry and all other players concerned.

Information and transparency

As outlined in the Commission's *White Paper on Health Strategy*, patients are becoming more involved in decision-making regarding their health. They have a right to more quality information on available medicines, the grounds on which they have been authorised and how they are monitored.

However, information provided by public authorities currently varies considerably, and media such as the internet may not always provide reliable or comprehensible data. This is to say nothing of the fact that the internet is not accessible to all. This was also underlined in a report prepared by the Commission in response to a request from the European Parliament and the Council.

Public authorities and health care professionals have a crucial role to play in providing patients with relevant and impartial information. The Pharmaceutical Forum endorsed recommendations to enhance the generation, access and dissemination of good quality information on diseases and treatments. The use of quality principles and increased cooperation among all partners for developing patient information should lead to tangible improvements for citizens.

On this basis, the Commission considers that the role of industry in this context should be clarified. Advertising is prohibited in Europe for prescription drugs. The provision of information by industry on prescription drugs is not harmonised at EU level and industry therefore has to contend with different legal systems in the twenty-seven member states. All might agree that this is hardly a situation that can accommodate web based initiatives that cannot be contained within frontiers. Possibly the only barrier remaining in the EU is language.

The European Parliament has therefore asked the Commission to look into the

issue of rationalising the availability and improve the quality of information to patients within the EU on prescription-only medicines, while maintaining the prohibition on advertising. A Commission proposal is due to be adopted in the coming weeks.

I come now to the last issue that is dear to my heart and to patients and consumers equally. It is the question of transparency. For a long time this industry was perceived as being keen not to disclose information that might harm the commercial value of its drugs. I speak of the past because I think that a lot has happened on this in recent years and, in particular, attention has been brought to the issue by the VIOXX crisis. It is fair to say that if patients are to take risks on drugs they need to know these risks in order to make an informed decision. They need to be confident that full light has been shed on results arising not only during the premarket phase but also in the post market life of a drug. It is therefore of paramount importance that, in parallel to what one or the other company may decide to do to improve the situation, we as the European Commission place mandatory obligations on national regulatory agencies, sponsors and market authorisation holders. We will do so on every occasion we can. We started with the paediatrics regulation; we continue with pharmacovigilance (publication of the opinion of the pharmacovigilance committee, patient reporting and patient participation in hearings); and will go on in a couple of years with the revision of the clinical trials directive. When doing so, we feel we can only help the industry in improving its image.

Policy makers and industry together have to make further progress towards a single and sustainable market in pharmaceuticals. We have to take on the opportunities and challenges of globalisation and we have to make science deliver the best for European patients. Finally we have to restore the EU's role as the natural home for pharmaceutical innovation.

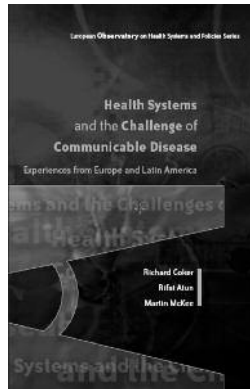
POSTSCRIPT

The Commission proposals concerning pharmacovigilance, counterfeiting and information to patients, the 'Pharma Package' were adopted by the Commission on December 10, 2008. More information at http://ec.europa.eu/enterprise/pharmaceuticals/pharmacos/pharmpack_en.htm

Health systems and the challenge of communicable diseases

Experiences from Europe and Latin America

Edited by: Richard Coker, Rifat Atun and Martin McKee



"This is an excellent book, well written and well documented.

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Nils Rosdahl, Specialist in Public Health, Past-President, Danish Society of Public Health 1995–99, European Journal of Public Health 2008;18(6):122.

Health systems everywhere face constant change as they seek to respond to evolving patterns of disease. This is especially true with communicable diseases where humanity is engaged in a constant evolutionary struggle with microorganisms that are able to adapt rapidly to a changing world.

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Changing regional health governance in France

Zeynep Or

The Minister of Health, Roselyne Bachelot, is about to put her name to an ambitious reform package which, if adopted, would transform the organisation and provision of hospital care in France. The controversial draft law, which will be subject to a vote in the French Parliament in January 2009, aims to improve the supply and coordination of health care at the regional level. To do this, the text suggests modifying not only the organisation and governance of hospitals but also medico-social services and ambulatory care.

The focus of health care policy in France has long been about controlling a public health insurance deficit that is estimated to reach €4.1 billion by the end of 2008. After decades of successive reform plans which mainly proposed short term remedies aimed mostly at restricting demand, the necessity of more structural reforms has been recognised by most parties/stakeholders. In particular, the split between the management of health care provision and the supervision of health care expenditure has been identified as a major structural weakness in the French system. The compartmentalisation of ambulatory, hospital and social care and the lack of articulation between central, regional and departmental levels have also been seen as major drawbacks, both in terms of cost control and quality of care in France.¹

Towards a unique regional health authority

'Regional Health Agencies' (*Agences Régionales de Santé*, ARS) are at the core of the reform package put forward by Minister Bachelot. These agencies have been on the political agenda for more than a decade. If the reform package is approved by Parliament in January, the ARS will be

rolled out in 2010. Currently, most hospital activities are controlled by regional hospital agencies (*Agences Régionale d'Hospitalisation*, ARH), but several different state agencies are responsible for the provision and financing of different types of long term and social care. Although the idea of creating regional health agencies, with an enlarged responsibility for controlling all types of inpatient as well as outpatient care, has been around for a long time, it has proved difficult to implement. The idea was however revived by President Sarkozy. His presidential programme includes a 'modernisation' agenda for greater liberalisation within the hospital sector.

These new agencies will bring together, along the lines of a 'one-stop-shop', the various stakeholders that are responsible for health care policy at the regional and departmental level. These include representatives of public insurance funds and local state authorities responsible for social and home care services. The objective is to simplify regional health management while strengthening the coherence of territorial policies. The ARS will have a mission to define 'health care needs' at the regional level and guarantee fair access to care, improving coordination between hospital, ambulatory and social care providers. They will oversee both public and private hospitals, as well as nursing homes. Each hospital will have to sign an annual contract to secure funding. The ultimate objective is to make the ARS act as responsible purchasers, contracting with individual hospitals rather than passively paying for services.

Primary care gets a nod in the reform package

The ARS will not have the responsibility for purchasing primary care or for managing the budgets for ambulatory care delivery, as these have been based on historical principles of private practice

(*médecine libérale*). The reform aims, however, to redefine the organisation of ambulatory care which, until now, has been treated as a separate issue. For the first time, the term 'primary care' (which did not exist in French) will appear in the public health code. The responsibilities of general practitioners will be defined in law, with the aim of enhancing their role and status.

The draft law also focuses on tackling inequalities in the geographic distribution of physicians. This has been a chronic problem in France due to the 'sacrosanct' principle of 'freedom of establishment' for physicians. The objective is to introduce financial penalties to discourage physicians from establishing practices in areas with high doctor density. But given the sensitivity of the subject, the proposed reform is rather timid, with responsibility for future regulation to be passed to the ARS. There are also proposals to improve after-hours care at the regional level to relieve congestion at hospital emergency service departments. Despite these symbolic efforts, overall the proposal is judged as being insufficient for developing real primary care practices that could improve both the quality and coordination of care.

New hospital communities

Another significant structural change will be the creation of new legal entities called 'local hospital communities' (*communautés hospitalières de territoires*, CHT). They will be formed by regrouping a range of small and large scale hospitals on the basis of the complementarity of their competencies. The idea is to concentrate complex surgical interventions in high volume hospitals and transfer less complex medical and medico-social care to small local hospitals. In principle, hospitals within a CHT will be able to share their patients as well as their health care resources. For example, a small hospital could transfer its most severe patients to a larger facility, while such facilities could lend specialists

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to these smaller hospitals for a couple of afternoons a week.

The problems of quality in low-volume, small hospitals for complex surgery have been a preoccupation in the past couple of years, particularly since the publication of the influential Vallancien report.² Volume thresholds have been introduced by national agencies for carrying out complex cardiovascular and cancer surgery. This has led to the centralisation of these services, but to date there has not been any real reflexion at the regional level on how to deal with hospital closures and problems of access.

This is one of the most controversial aspects of the reform as the hospital federations perceive the proposal as the official 'end of the small hospitals'. Hospital closure is a very sensitive issue and there have been several demonstrations against the reform project even before the consultation process started. Following adverse reactions from both the hospital federations and the trade unions, the Minister of Health has now given an assurance that there will be no hospital closures, only a transformation in their function.

Furthermore, the rules of management in

public hospitals will be simplified and hospital directors will gain real autonomy in management, with better defined objectives and results-based evaluation. One novelty is that they will have more flexibility in recruitment decisions, including the possibility of establishing part time contracts with private practitioners. Modes of remuneration for physicians will also be more flexible, allowing for the introduction of performance-based payment. In turn, hospital directors will sign annual contracts with the ARS setting out specific activity and quality objectives.

Some scepticism remains

Despite the fact that most of the measures proposed in the reform package do focus on long-awaited structural changes to strengthen regional governance and emphasise the importance of coordinated care in the system, the initial reactions of almost all stakeholders have been highly critical. This is partly due to a poorly organised process of consultation, in which most stakeholders were unhappy with the lack of dialogue and debate on the draft law.

One major issue, still under negotiation, is how power will be shared within the new

regional health agencies. National sickness funds are particularly worried about how much power they will have within the future ARS. They are also concerned about the potential risk of increased state control, given that the directors of ARS will be nominated by the government's council of ministers (cabinet).

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Regionalisation reversal in Canada

Gregory P Marchildon

In Europe, health service regionalisation – that is, states decentralising the delivery of public health care services from ministries of health to delegated administrative bodies – has existed for a long time. In those countries where regionalisation was adopted, such as the United Kingdom in the mid-1970s, higher-level policy and monitoring functions in the Ministry of Health were separated from management and delivery functions on the ground. This was based on

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a simple but powerful idea “that smaller organisations, properly structured and steered, are inherently more agile and accountable than larger organisations”.¹

Decentralising management and service delivery is an idea that has been adopted in various forms in a number of Western European countries, from Sweden and Denmark in the north, to Spain and Italy in the south. It is now at the centre of a major debate in France, where a draft law on the creation of 'Regional Health Agencies', vigorously contested by some of the most powerful stakeholders in the country, will be debated in the French Parliament in January 2009. This controversy provides an opportune time to review the Canadian experience with decentralisation and regionalisation, including the most recent

debate that has been triggered by the decision of one province, Alberta, to eliminate its regional health authorities in favour of a more centralised management and delivery system.

Decentralisation in Canada

Even before the introduction of regional health authorities in Canada during the 1990s, the public health care system was relatively decentralised. As provincial governments have the primary responsibility for health care and other social policy under the constitution, they have been responsible for administering tax-based, single-payer administrative systems for universal public health care services for decades. When the three northern territories are considered in addition to the ten

provinces, this means that Canada has thirteen separate public health care systems that vary dramatically in population and size; for the provinces, these range from Ontario (1.1 million km²) with its thirteen million people – the population size of a number of European states – to tiny Prince Edward Island (5,660 km²) and its 140,000 residents – less than one-half the population of Iceland.

The province of Saskatchewan's innovative introduction of universal hospital and medical care insurance combined with the federal government's agreement to cost share expenditures, led to the eventual establishment of universal hospital and physician care in Canada in the 1950s and 1960s. In the 1970s, provincial governments began to administer, subsidise or otherwise support other health care services, including prescription drug plans, home and long-term care. Although numerous commissions and studies of the day recommended that provincial governments introduce regionalisation in order to better co-ordinate and integrate the organisation and management of these services, it would take at least another two decades for regionalisation to be implemented, in part because of opposition from existing stakeholders, particularly physicians and private not-for-profit hospitals. In the midst of a fiscal crisis caused by decades of accumulated public debt, nine provinces and one territory established regional health authorities (RHAs) between 1990 and 1997.

While the number of RHAs, and the populations they encompassed, varied dramatically in each province, each RHA had its own board of directors responsible for governance and a single executive management team under the direction of a chief executive officer. Each RHA acted as a provider, as well as a purchaser, of services.

As a structural reform intended to achieve substantive health service reform, regionalisation everywhere in Canada shared three common characteristics: (1) through RHAs, rationalise, coordinate and integrate what had been a fragmented set of health care organisations – from hospitals and long-term care institutions to home/community care and public health activities – in order to improve the quality and appropriateness of care; (2) decentralise health budgets from provincial ministries to RHAs so that health resources would be allocated on the basis of local needs as defined by those closer to

the population receiving services; and (3) reallocate scarce resources from downstream hospital and institutional care, to more upstream primary care and public health services, and determine the services and policy interventions appropriate to the population being served within a geographically delimited area.

In the years following the reforms, some difficulties and trends were discernable, including considerable tension between provincial ministries of health and RHAs concerning respective responsibilities and authorities. Although there was no consensus concerning the optimal number of RHAs, most provinces eventually reduced the number of RHAs originally established. There remain significant difficulties concerning the direction and speed of primary care reform; indeed, the majority of physician remuneration in all provinces continues to be fee-for-services and the ministries of health, rather than RHAs, remain responsible for physician remuneration. Finally, there has been no major study concerning the impact – at least in terms of improvements to service delivery – of regionalisation.

In 2005, Ontario belatedly joined the majority of provinces by establishing fourteen Local Health Integration Networks (LHINs). The Ontario model of regionalisation differed from the model in the rest of the country. Unlike RHAs, LHINs are limited to purchasing and co-ordinating services within their geographic areas. At the same time, the province of Prince Edward Island disbanded its RHAs and centralised all administration and most delivery in its health ministry. However, most commentators at the time concluded that Ontario's adoption of regionalisation meant that this structural reform was here to stay in Canada.

Regionalisation reversal

This remained the case until May 2008 when the provincial government of Alberta suddenly announced the elimination of its nine health regions. Immediately replacing the RHA boards, and soon to replace the administrative structures in the regions, the Alberta Health Services Board will administer all health services in a province with almost 3.5 million residents. By Canadian standards, this is centralisation on a grand scale, and the decision shocked observers because no study or commission recommendations preceded the change. The arguments used by the Alberta government to justify the shift are almost identical to those

used by the Irish government when it eliminated its health boards in favour of a single organisation – the Health Service Executive – responsible for service delivery throughout Ireland. These include clarifying roles and responsibilities by consolidating and amalgamating a complex of boards and their executives into a single governance and administrative unit; obtaining greater value for money through streamlining and consolidating services within the province; introducing more patient-centred ('21st century') care; and ensuring greater consistency and quality of service throughout the province.

What does the future hold for regionalisation in Canada? The answer is far from clear but the Alberta decision may stimulate major structural changes in other provinces. It also offers a natural experiment. If the new structure introduced by the Alberta government can even be considered a type of regionalisation, we can say there are now three models of regionalisation operating side-by-side in Canada. There is the decentralised RHA model in eight of Canada's ten provinces in which there is a purchaser-provider division between the ministries and health regions. There is the even more decentralised LHIN model in Ontario model, with a further 'pure' purchaser-provider split between the LHINs and individual health organisations. And there is now the centralised model in Alberta in which one organisation, the Alberta Health Services Board, is responsible for all service delivery in the province, and another, the provincial ministry, responsible for broad policy direction. All three models of regionalisation can be compared to a control – the one province and two territories which continue to have health ministries responsible for all public health care delivery. If governments within Canada can desist from further structural change for the next five years, and if good comparative research can be completed, this experience should prove useful to other countries considering some form of regionalisation reform.

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Czech Republic: First steps on the path to health care reform

Lucia Kossarova and Henrieta Maďarová

After some quiet years, the pace of post-1989 health care reform in the Czech Republic seems to have picked up. In addition to the common challenges faced by health systems across Europe (ageing populations, rising expectations of citizens and technological advances), the health care system in the Czech Republic is struggling with an inefficient use of health care resources, the implications of the global financial crisis and overconsumption of health care by the population. Together these factors may threaten the system's performance and sustainability.

Proposed reforms to address these issues are intended to increase efficiency and stabilise the system; while improving both access to and the quality of health care services; and strengthening the role and responsibilities of the patient.¹ A key first step in achieving these goals is to modernise health care legislation that dates back to 1966,² so that it better reflects the needs of the population. This snapshot will briefly describe proposed legislative change and the ensuing political debate.

Reforms will bolster patient rights

A number of health care reform bills have now been prepared as part of a package of interrelated laws (See Table). The five new bills being considered by the legislature would reorganise the regulatory framework into more logical groupings, i.e. the general rights of patients would be separately stated, while the specific rights of insurees would be placed within

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proposed new laws for public health insurance (PHI).

Following an extensive and rather emotional discussion on background policy documents³ prepared for the new bills*, the Ministry of Health decided to proceed in two stages. First, to begin the discussion and legislative process related to the rights of patients, patient-provider relationships and the obligations of service providers set out in Bills 1, 2 and 3 and then subsequently to move to Bills 4 and 5 that propose changes to the regulation of the public health insurance system.

Currently, relevant legislation is not to be found in one place, but rather is fragmented across numerous regulations, where the patient is still viewed as a passive participant. The new *Bill on Health Services and Requirements for Their Provision* can thus be considered as an umbrella bill directly linked to the subsequent bills on special health and emergency services. Primarily the emphasis of this umbrella Bill is on the safety and rights of the patient, making him or her for the first time a 'consumer' of services across

the entire system. For example, it benefits patients by giving them the right to refuse health care services and obtain clear information about health services and their prices. It also specifies how complaints should be dealt with and when providers can be sanctioned. Interestingly, the Bill also sets out obligations and responsibilities for patients, in particular in respect of actions which may positively impact on their health; for example, the obligation to make preventive health care visits and/or to adhere to treatment. The Bill also clearly specifies the conditions under which providers can obtain or indeed lose a permit to deliver services, as well as those situations in which they can legitimately deny care to patients.

Other elements of the Bill include new definitions of the types and level of health services, thus delineating the frontiers of the health system. For example, general transportation services from or to a health care facility are no longer considered as health services and can be provided by non-health care employees. These new definitions will be directly relevant when specifying services to be covered by PHI. Finally, the Bill should help improve quality and safety in the system. For example, 'care standards' for service providers that reflect the most up to date knowledge in clinical medicine are recommended. These standards will refer to clinically effective guidelines specified by the Ministry of Health, health insurance companies and service providers.

Special services which require more stringent regulation and ethical considerations are to be covered in a *Bill on Specific Health Services*. The proposed Bill focuses on safeguarding patient rights in respect of sensitive services such as assisted fertilisation, sterilisation, cloning, blood

Table. Overview of proposed health care legislation⁴

1. Bill on Health Services and Requirements for their Provision
2. Bill on Special Health Services
3. Bill on Emergency Services
4. Bill on Public Health Insurance
5. Bill on Health Insurance Companies and the Health Insurance Companies Surveillance Authority

* Before any new legislation is drafted the government must first approve policy documents setting out the issue, current legislation and a description and arguments for proposed reform.

donation and pregnancy terminations. Attempting to harmonise this Bill with EU legislation has led to vigorous debate. For example, allowing any EU female citizen to obtain a termination in the country under the same conditions that apply to Czech women has raised a myriad of ethical and ideological issues which continue to be discussed in Parliament.

A third *Bill on Emergency Services* aims to improve access to emergency services (ES) for the entire population, adjusting the way these services are provided and financed, while improving coordination between different health care entities. For example, while current legislation states that all individuals should have access to ES within fifteen minutes, as much as 12% of the population have to wait up to thirty minutes. The new bill would take into account demographic, geographical and other risk factors and set a more realistic limit of between fifteen and twenty minutes. By re-designing the ES network and creating forty-four new ambulance stations, almost the entire population could be reached within fifteen minutes, with a mere 2% of the population having to wait twenty minutes. Furthermore, the ES network will be financed by health insurance companies and the state budget rather than in the current system, where it is funded by regional governments, often leading to differences in per capita spending and access to services.

The three proposed Bills, if enacted, would enshrine the role of patients as decision makers and the patient-provider relationship within legislation, unlike the outdated 1966 law. Repealing the 1966 Act would also require the repeal and amendment of a number of other health laws and regulations, including, most importantly, amendment to *Law 48/1997 on Public Health Insurance*.

The revised terminology in all three proposed bills would enable much needed improvements and clarifications in the definition of the basic benefits package (BBP) covered by PHI. In general, the scope of services covered by PHI would stay the same but the proposed definition is more precise. It states that health services covered by PHI should be responsive to the health needs of patients, based on the latest medical knowledge and provided in compliance with the cost effective utilisation of health system resources. The new definition of BBP will be supported by two lower level instruments: a bylaw on the catalogue of health services, as well as

clinical guidelines that should ensure the provision of the most clinically effective care, taking into account individual circumstances.

At present, only standard treatment is covered by PHI and all alternative treatment options are usually paid in full by the patient. The new definition would mean that patients would only have to cover the differences in cost between alternative and standard PHI reimbursed options. These rules are similar to those already in use for drug reimbursement policies that have led to improvements in efficiency. The proposed definition of BBP, coupled with new clinical guidelines, will help to standardise the quality of care, something which at present is left entirely to the discretion of service providers. Not least, patients will know what services they are entitled to under PHI and thus avoid unnecessary co-payments for these services. The amendment bill to Law 48/1997 includes new exemptions from user fees for the most vulnerable groups (primarily children, dependent older people and others living in long term care facilities) and reductions in the limits on user fees and out of pocket spending for selected co-payments for drugs.

The first three bills and the amendment to Law 48/1997 have already been presented to the Parliament and are expected to be approved in the first quarter of 2009. Both within the governing coalition and the opposition, the most controversial discussions at present gravitate around the new definition of the BBP and the list of exemptions from user fees. Most of the concerns with this new definition relate to the provision that full reimbursement applies only to the most cost effective treatments for the individual, depending on their needs. On the one hand, it is generally accepted that resources in the health system are limited and should be used more efficiently. On the other, a minimum level of quality and standards of health services, as well as access to information on alternative treatment options, is expected to be guaranteed and defined through bylaws. This should avoid excessive and fraudulent co-payments for treatments that have been viewed as being 'above' standard but which in fact are standard treatments.

The discussion on user fees is focused on the identification and exemption of those groups that are perceived as being most vulnerable. The definition of this group may however change in light of the high

inflation in food and fuel prices during 2008 and the impact of the global financial crisis on the economy, employment and wages. However, due to the disputes within the coalition and loss of their majority, all user fees were repealed in the lower chamber of Parliament at the end of December 2008. It is hoped that the upper chamber will be able to reach a consensus on the list of exemptions from user fees and revoke the lower chamber decision. A meeting is planned for the end of January 2009.

Reform of private health insurance

Despite the benefits of these three proposed laws, current legislation governing PHI is still not deemed to be sufficient and will require further improvement. That will only be possible when discussions on Bills 4 and 5 – the *Bill on Public Health Insurance* and the *Bill on Health Insurance Companies and Health Insurance Companies Surveillance Authority* commence. These bills together would provide for systematic changes in the organisation and operation of the PHI scheme, with the primary goal of empowering insurees and increasing efficiency in PHI spending.

The Bill on Public Health Insurance would further improve the definition of the BBP by specifying a maximum travelling distance to general practitioners, specialists and inpatient facilities, as well as a maximum waiting time for diagnostic and elective health services. In order to make the system more transparent, patients would also be able to access a range of information including data on the quality of health care providers, the performance of health insurance companies and prices of alternative treatment options.

The new Bill on Health Insurance Companies and the Health Insurance Companies Surveillance Authority would require health insurance companies to operate as specialised private companies answerable to their shareholders and adopting standardised accounting and regulation principles. The bill also proposes stricter financial regulation and control of services provided to insurees, for example, monitoring waiting times and ensuring access to a network of providers within a maximum travelling time.

In summary, there is general agreement in the country that the health system needs systematic change after years of small ad hoc adjustments. Given all the challenges that the system is facing, beginning this

process of reform through discussion of these proposed laws is important. While the disagreements within both the governing coalition and opposition threaten the approval of this legislation in its current scope, discussions on these bills should continue so that, in time, a proposal acceptable to all can be agreed upon. The Czech health system requires modernisation and so does its legislation.

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The Finnish welfare state meets the consumer society

Hannu Valtonen

The long tradition of local government in Finland seems to be reaching a turning point: the government is implementing reforms intended to strengthen the municipal structure (i.e., increase the size of the municipalities), to alleviate equity problems and to give clients more freedom of choice. The most frequently evinced reasons for these reforms are similar to those set out in many other European countries - the ageing population, securing sufficient supply and availability in the labour force, securing the financing of services, improving the position of clients/patients and meet the challenge of globalisation. The current reform policy presents itself as a rational reorganisation of service structures and financing. Its success will depend on how well it meets the demands and expectations of health care consumers, health care personnel and provider organisations.

In Finland, local health policy decision-making has been decentralised since the beginning of the 1990s; indeed it is sometimes claimed to be the 'most decentralised health system in the world'. The Finnish

municipalities (431 in 2006 for a population of 5.3 million; but only 348 municipalities from 2009), are responsible for the provision of both health and social services, and in this they use their own local tax revenues and are supported by state subsidies. Hospital services are provided within twenty-one hospital districts. The financial flows to primary health care, hospital services and social services all go through the municipalities. In principle, if maybe not in practice, the municipalities, with their long and strong tradition of local self government, have been important political and managerial decision-makers in health and social policy. Their position was strengthened even further at the beginning of the 1990s with the decentralisation of decision-making on the organisation, extent and content of services that they provide. One of the arguments for this decentralisation process was that of responsiveness: the municipalities would be able to adjust their services to meet local needs and conditions. Compared with this, the present trend in reforms is just the opposite, back to a more centralised organisation.

Challenges to municipal health services

Some observers contended that the municipalities, have not in this period been capable, innovative, willing, courageous or radical enough in their actions. Alterna-

tively, others have argued that they did not have the necessary political power to fulfil the expectations imposed on them – to organise fairly distributed, responsive, efficient and financially sustainable health and social services. The ongoing reform wave includes several health and social care structural and functional programmes and reforms for the whole social security income transfer system. In health care the reforms concentrate on municipal local health and social services, and in particular on how to strengthen their financial basis.

The challenges faced by the municipal health services had culminated in political discussions concerning two key problems: doubts over the capacity of municipalities to finance and to control the rate of growth for all services, and in particular for hospital services; and secondly, the operational difficulties of local health centres (local primary care units), notably in access to health centre doctors and in ensuring a sufficient level of recruitment to the labour force. Furthermore, as a whole, their public image is weakening.

These problems have also been recognised by external commentators: for example, one review by the OECD¹ identified a need to strengthen both the capacity of health centres and improve their efficiency, not only because of financial sustainability requirements, but also to address equity

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concerns. A number of the OECD recommendations were directed at developing health centres (for example, improving access, expanding the role of nurses to meet consumer expectations, centralising the financing of services, and merging smaller municipalities).

The PARAS reform programme

In spring 2005, the government launched a long term reform programme – PARAS (literally meaning 'the best'). Unlike earlier reforms in Finland, the government has not aimed to regulate reform content at local level in detail, instead the municipalities have been asked to compile their own plans for the reform of health and social services. What is, therefore, new in this reform process is that central government provides only general guidelines on what the municipalities are expected to do.

For example, in primary health care services and some social services, a lower limit for the population catchment served by one organiser (for example, a municipality) is determined (20,000 inhabitants). Central government has left it to the discretion of the municipalities to determine how best to meet this requirement. Options might include merging municipalities; creating a new organisation owned by small member municipalities (a federation of municipalities); allowing one municipality to provide services for a number of neighbouring municipalities; allowing hospital districts to organise services, etc.

This approach is unprecedented in the history of the Finnish welfare state, where central government has always regulated services and structures have been very uniform, regardless of whether or not the system has been centralised or, as from the beginning of the 1990s, decentralised. After the whole reform process is complete, we shall have a welfare state which, in an organisational sense, is more heterogeneous than before.

To a large extent, the PARAS Programme would appear to be the government's response to the problems of local health centres. However, we must ask whether these forthcoming changes can save these public health centres? This is what the government is aiming for. In Finland, more than before, there are both functional and political pressures on public health services that consist of changes in individual needs, expectations and consumption habits. It is not only that an ageing population can be expected to increase the demand for health

and social services, but maybe even more so that the demands on health care are changing because the expectations of younger generations are different from those of their predecessors.

Reforms in a consumer society

The governmental reforms are being implemented in a society that can be called a 'consumer society' in health services. Mechanic² describes this kind of society (his example is the United States) as having several particularly important features which "include belief in marketplace competition, choice, activism, technological progress, and consumerism. Many Americans, informed by the dominant economic paradigm, see health care as no different than other market products to be appropriately allocated through the same economic processes".

I do not presume to compare the Finnish and US health care systems – the public financing and provision of services in Finland decidedly continues to prevail. But, we are increasingly seeing a consumer society type phenomenon in our health care system. The problem is to reform the welfare state model to accommodate consumer society behaviour.

Phenomena indicating the rise of this kind of consumer society in Finland include increasing demand for private health insurance (especially for children), despite 100% coverage by the public services. In the long run this can be expected to undermine political support for public services, maybe even the whole legitimacy of the welfare state model; after all why pay taxes to finance health services, if the whole family can have private insurance? Another feature in the changing behaviour of patients is reported by Toiviainen.³ In her sample "more than half of physicians conducting patient work reported that they (very) often encountered patients who stated upon arrival for a consultation that they wanted specific treatments or examinations, and that the number of such situations had increased."

On the provider side, too, there are some changes taking place that challenge the Finnish welfare model: the provision of services is diversifying. As one result of the PARAS reform in the 2010s, we shall see varying organisational forms in the provision of public primary health care services. In addition, not only the number of private health service providers, but also the number of various providers that are hybrid public/private organisations are

increasing. On the provider side, competition in the health care labour force is also intensifying. At the same time that some health centres are facing shortages in staff, some of these new types of firms have started to recruit staff, notably doctors, from within the existing labour force. One implication of this is that municipalities may have to outsource some health centre services. For doctors however, this offers greater flexibility in working conditions, working hours and working days, and potentially also in income, compared with those traditionally offered by health centres.

The crucial question, therefore, that will determine the success of the wave of reforms that have taken place during the past decade will be whether or not they have been a culturally acceptable response to the new and changing expectations in respect of both the demand and supply of health care services.

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New and old challenges in the reform of mental health systems in Spain

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Summary: This article provides an overview of the state of mental health reform in Spain. It describes the motivation and the process of different reforms, briefly brings to the fore the most relevant evidence on their consequences, and ends by identifying key areas of policy reform.

Keywords: Mental Health, Reform, Spain

While mental health seldom occupies a significant space within political debates, increasingly it has featured high on health policy priorities across Europe.¹ However, mental health systems are very much country-specific and influenced heavily by prevailing societal attitudes towards poor mental health. Rapid economic, political and social changes in Spain have meant a move away from the conservative society that existed in 1979 to a liberal democracy over the course of three decades. As a result, the principles underpinning the organisation of mental health systems have shifted away from a reliance on long stay institutional care in asylums, where the overarching concern had been to protect society from potential ‘harm’, to a system where the bulk of care is being provided through the development of a network of community based centres to help support people with mental health problems.

One continuing challenge in looking at mental health reform is obtaining data on the structure of mental health systems. Such data is of highly variable quality

across Europe, making cross-country comparisons difficult. One comparative study (the ESEMED study) looked at services in six European countries – Spain, Italy, Belgium, Germany, France and the Netherlands. This study indicated that the provision of services for people with mental health needs was low in Spain (as well as in Belgium and Italy).² Expenditure on public mental health services in Spain remains modest at around 5% of total health care expenditure,³ although there is some significant variation between the seventeen Autonomous Communities (ACs); expenditure in Catalonia, for instance, has recently been estimated to be closer to 9%.⁴ No wonder mental health care is regarded as the Cinderella of the Spanish health system, namely a second order priority and generally among the last to be reformed.

This article provides an overview of the state of mental health reform in Spain. It describes the motivation and the process of different reforms, briefly brings to the fore the most relevant evidence on their conse-

quences, and ends by identifying key areas of policy reform.

A chronology of mental health reform

The 1986 General Health Care Act, charged the National Health System with working towards both the promotion of good health and the prevention of disease. The aim was to achieve equity of access and help overcome social and geographical differences across the country. Access to health care became free at the point of use to all residents of the country (including undocumented immigrants) and user co-payments were restricted to pharmaceuticals. Benefits remain comprehensive, although coverage for some services such as long-term care and dental services is limited and varies according to region-specific demands.

Today, mental health services, like the rest of the health care system, are the responsibility of the seventeen ACs. There are therefore at least seventeen different mental health plans, each one tackling AC specific problems, with cross-regional learning taking place. However historically mental health had been somewhat neglected; the system relied on the willingness of the non-governmental sector, typically religious organisations, to fill the gaps left by the limited, fragmented and poorly coordinated public services managed by different administrative bodies.⁵

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A 1983 Ministerial Commission on Psychiatric Reform, followed by the Psychiatric Reform Act of 1985, gave rise to what can be regarded as a modern model of mental health care. The Act aimed to guarantee access for people with mental health problems to services within the general network of health care, and specifically within primary care. It also redefined the therapeutic meaning of psychiatric hospitalisation, which lost its central role in psychiatric care. This was coupled with the objective of providing adequate community services and social supports for the rehabilitation and reintegration of people with mental health problems into the community. Actions were also envisaged in the community to tackle discrimination and protect human and civil rights. The reforms however only focused on people with psychoses who had been living in institutions; in fact they only make up a fraction of the total population of people with mental health problems at risk of being social excluded.⁶

Meantime, broad health system reforms introduced under the General Health Act of 1986 integrated mental health care into the mainstream health network. Mental health services, with the exceptions of hypnosis and psychoanalysis, were included within the package of general health services. Moreover a set of specific Diagnostic Related Groups (DRG) were defined so as to measure activity alongside other information system improvements.

The reforms helped in the completion of the de-institutionalisation process initiated in the late 1970s, which implied a shift away from a system based on old asylums to one centred on community care, as in some other western countries. Figure 1 illustrates the decline in the number of beds in psychiatric hospitals over the last quarter century, being just 39.6 beds per 100,000 population by 2006.⁷

This decline in beds implied the integration of the mental health system to follow a similar structure as the rest of the health system, namely an organisation that would rely on outpatient, inpatient and residential facilities, as well as multidisciplinary teams of health and social care resources. Workforce regulation and accreditation criteria were completely reformed to include doctors, as well as a new cadre of new mental health professionals, such as social workers and other health professionals, that only recently have been considered of equal value to other professionals within the health

system. Indeed these reforms led to the creation of a national training programme for psychiatrists, a network of mental health units to assist outpatient provision following GP referral, and the addition of psychiatric beds to several general hospitals. Psychiatrist activity rates expanded from 3.9 per 100,000 population in 1982 to 5.12 in 1994. There have been other newly emerging mental health care professionals in the last decade. As of 2005 these included: psychiatric nurses (4.2 per 100,000 population), neurologists (2.5 per 100,000 population) and psychologists (1.9 per 100,000 population).

A network of mental health centres each covering population catchments of between 200,000 and 250,000 people developed rapidly. By 1994 there were 550 such centres; however, given the devolved nature of the Spanish health care system, the implementation of the reform has been geographically uneven and there appear to be marked differences between the different ACs in the availability of services due to differences in regional priorities.

In 1994, a national essential drug therapy catalogue, including treatments for mental health problems was established. A further reform under Royal Decree 63/1995 defined mental health as a type of 'specialised care' made of diagnosis and follow up, drug treatment and individual (group or family) psychotherapy, and possibly hospitalisation.

Unlike other areas of health care policy, the voluntary sector plays a crucial role in the provision of community care, to say nothing of the informal contribution of family carers. When the mental health

service package was updated in 2006 (Royal Decree 1030/2006) it made particular reference to the role of primary care in identifying mental health problems, thus further emphasising the community care-led model. One of the key challenges that Spain faces, common to the situation in many other countries, is the lack of coordination between different levels of primary, secondary and specialist care, as well as between health and other sectors including social care, in assessing and meeting the needs of people with mental health problems.

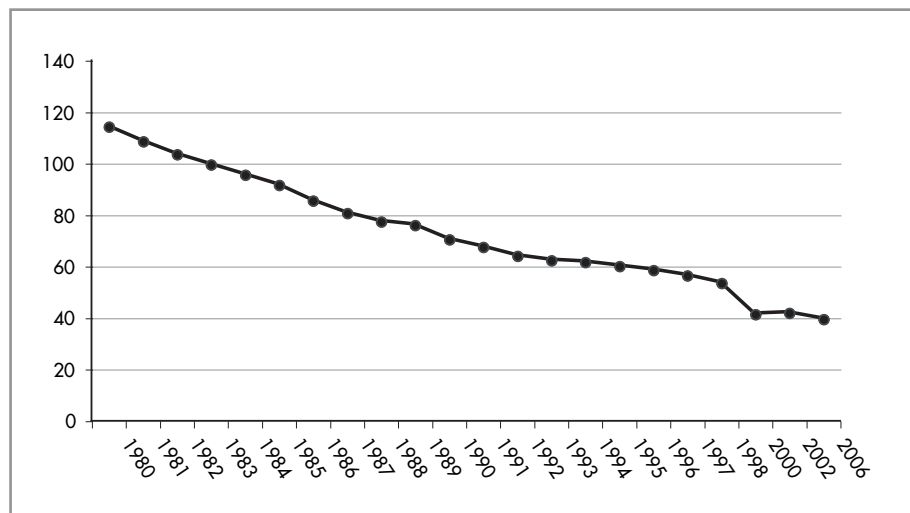
However, it was not until 2007 that the Ministry of Health put forward a working document, the so called 'Strategy to Tackle Mental Health' which contained new clinical guidelines for general practitioners and specialists on the identification and prevention of mental health problems. Similar strategic actions had long been set up for related problems such as the prevention of substance abuse.

The utilisation of services within primary care remains low in comparison, at approximately 17% of all those with mental health problems compared with 40-50% in most European countries.⁸ This does not simply reflect a lack of demand for such services, but also is a consequence of the restrictions in their availability.

Financing and coordination

Mental health is financed in the same way as other health care services in Spain, through taxation supplemented by out-of-pocket expenditure by service users and their families. Private insurance does not play a prominent role. We have noted that expenditure on public mental health

Figure 1: Psychiatric beds per 100,000 population, Spain



Source: Spanish Ministry of Health and Consumer Affairs, 2006

services in Spain remains modest at around 5% of total health care expenditure³ but that there can be significant variation in expenditure rates between the ACs, reflecting the differing levels of priority given to mental health.

Indeed, Salvador-Carulla et al,⁵ report higher mental health expenditure relative to total expenditure in Catalonia and a higher absolute expenditure in Navarra compared to Andalucía.

In terms of service mix, as we have already noted, community care services are still developing, which may explain the greater reliance on pharmacotherapy relative to other high income countries. While there has been a significant volume growth in the use of antidepressants in seven European Union countries, growth in Spain is almost three times that of France.⁹ Moreover some non-pharmacological services are not well covered within the public system, the most notable being psychotherapy which, unlike the situation in Germany and the Netherlands, may only be covered for very short periods of time.

We have noted challenges in administrative co-ordination. Across Spain arrangements for managing mental health services can vary considerably, with different degrees of responsibility resting with the AC governments, provincial governments and municipal authorities. Coordination within and across the health service is thus complex and rarely takes place.

Services provided within the health care system are also often not well coordinated with social care and other relevant sectors in social policy. The transfer of social services to the ACs was completed in 1997 but it was only with the completion of the health care decentralisation process in 2002 that the need for functional coordination came to the fore. The shift away from institutional to community based care has been markedly uncoordinated with asylum closures before community services have been fully developed.⁶ Although roughly half of the ACs have set up some mechanism for coordination, the absence of well run coordination between social and primary care remains the norm rather than the exception.

Empirical Evidence

Need for mental health services

Between 5–10% of Spaniards will experience an episode of depression at some point during their lifetimes.¹⁰ Rates are

much higher in women than in men, with urban residence not seen as a significant risk factor.¹¹ Rates are lower for people aged between thirty and forty-four. Other protective factors include being single, employment and a good level of educational attainment.¹² Similarly, the results of the ESEMED project³ indicate that 19.5% of Spaniards (23% of women and 16% of men) experience some mental health problem during their lifetimes, with 8.5% experiencing such an event in any one year (11.4% women and 5.3% of men).

Utilisation of services

Spain lags behind Italy, France, Germany, Belgium and the Netherlands in psychiatrists per 100,000 population (only one-third that of Italy and 15% of that France). It has around 50% of the psychiatric beds per capita available in France.¹³ About 6.4% of adults make use of the health care system because of a mental health disorder, of which 21.2% do not receive any specific treatment.² Alonso and Haro³ reveal that roughly one-third of the population have contacted a mental health professional; the lifetime rate of consultation is about 15% higher than Italy, and similar to that seen in the Netherlands (30%) and France (28%).¹³ Estimates of service utilisation were relatively high among those with mental health problems resulting from alcohol disorders.

Data from a 2006 Eurobarometer survey allow the comparison of mental health service utilisation in Spain with that of the EU average.¹⁴ Table 1 reveals that Spaniards have lower contact rates with their general practitioners to discuss mental health problems. However, if comparing just those who have diagnosed mental health problems, then rates are comparable to the EU average. Whilst they are on average less likely to use a pharmacist's advice, they appear to be more likely to visit a psychiatrist, especially when experiencing a mental health problem. Rates of therapist and psychoanalyst utilisation are similar to those in the EU as a whole, psychotherapy rates are lower, while contact rates for nursing for those known to have mental health problems are above the EU average.

Appropriateness of care

Another major problem that mental health systems must contend with concerns the appropriateness of care, and more broadly quality. In Spain about 13% of visits to formal care services are made by individuals who do not meet any diagnostic criteria for mental health problems.¹⁵ However, in practice, matching service utilisation with need can be complex as the presence of a mental health disorder does not always imply the need for mental health care. In fact, Spain has low service

Table 1. Percentage of mental health care use in Spain compared to EU average, 2006

Question: In the last twelve months did you seek help from a professional in respect to a psychological or emotional health problem?

	EU		Spain	
	All	Mental health problems	All	Mental health problems
GP	10.4	17.5	6.3	16.7
Pharmacist	2.0	3.2	0.7	2.1
Physiatrist	1.9	3.3	1.9	5.0
Therapist	1.6	2.7	3.4	2.4
Psychoanalyst	0.1	0.2	0	0.3
Nurse	0.6	1.0	0.1	1.6
Social worker	0.5	1.0	0.1	1.8
Psychotherapist	0.4	0.75	0.2	0.5
Any other professional	2.3	3.83	1.4	3.1

Source: Commission of the European Communities, 2006.¹⁴

consultation rates by those without mental health disorders, which on one hand might be taken as a measure of appropriateness of care, but on the other might well indicate little investment in prevention.¹⁵

Key policy challenges

One of the main problems in regulating mental health services is the greater level of information asymmetries between service providers and those with mental health needs. This is in part due to the high level of prejudice and stigmatisation that continues to surround mental health, particularly in a country like Spain which has only begun to modernise relatively recently. Furthermore, the important role of partners and family members in providing support for people with mental health problems is widely acknowledged. The need to tackle stigma, as well as prevent mental health problems occurring, are key priorities, particularly for those who already may be at greater risk of marginalisation, including immigrants and the unemployed. In Spain one survey suggests that poor physical and mental health can impact on the social activities of just over 30% of the population, a rate much lower than that observed across the EU as a whole. However, it is complex to disentangle the extent to which this evidence responds to a lower prevalence of mental health disorders or, a higher under-reporting of mental health disorders due to stigma.

Of particular importance are population sub-groups such as children and older people. Children who have parents with enduring mental health problems may experience lower quality parenting which is likely to affect their future life and working opportunities. Equally, mental health problems observed at school might have adverse impacts for crime and increase the risk of social exclusion. Young people, who may find it difficult to break into the employment market due to a lack of experience and qualifications, are another key group. Young people identified as having psychosis require both early health and social care interventions to prevent and treat potential conditions that can result in more severe symptoms and disorders. Another important group are older people; this is especially relevant in Spain given rapid population ageing. For older people poor mental health may compound existing physical health problems and disabilities; it may often go untreated, increasing the risk of dependency.

Another source of increasing demand for mental health services is work-related stress. Spain has all of a sudden become 'Europeanised', leading to a significant change in lifestyles, especially in working conditions, some of which might have transitional costs in terms of stress and adaptation. Another source of increasing demand for mental health services is unemployment, and Spain has traditionally been a country with high unemployment rates. Finally, another important consequence of the westernisation of Spanish habits lies in the adoption of western lifestyles and identities, which can be responsible in some circumstances and in some social groups for increased illegal drug consumption, as well as an increasing risk of eating disorders.

As with physical health, there is an income gradient that explains the influence of social hierarchy in explaining the prevalence of mental health disorders. This especially is the case for depression.¹⁶ Indeed, depression in Spain appears to be more prevalent among the poorest, even when income related inequalities are decomposed into education and a set of other relevant determinants. Among potential explanations for this feature is the fact that the quality of child care is found not to be independent of income, and the absence of an efficient health care network for prevention, diagnosis and appropriate treatment of mental health problems among the less affluent.

Concluding remarks

This article provides a brief overview of the organisation and reform of mental health care in Spain, focusing on recent reforms and current challenges. Given that mental health care does not come cheap and it is far from obvious how mental health programmes are prioritised vis-à-vis other health related programmes, reforms should veer more towards increasing the integration and coordination of mental health care within health and social care services. From the existing evidence, further coordination between specialised and primary care is required and targets for prevention might be set inter-sectorally given the existing spillover effects of mental health problems on other sectors, as well as their impact on physical health.

Ignorance, along with the irrational fear and stigmatisation of mental health problems that is common across the globe, goes some way to explaining limited public sector actions. Mental health services have

paid a high price for not being adequately funded, as the authorities (albeit to a lesser extent after decentralisation), rather than organising strong mental health policies themselves, have opted instead to shift care to the social arena where it is the subject of means testing.⁵ Arguably this can be seen as an implicit means of privatisation. Given that the priorities for social care differ across the ACs, there is a need for more robust coordination of health and social care. After all, better support for people with mental health problems, it is acknowledged, can in turn reduce the likelihood of common co-morbid chronic physical health problems.

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Liberalisation of health care in the Netherlands:

The case of mental health care

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Summary: A process of liberalisation is taking place in health care in the Netherlands. The impact of this process varies over the various health care domains. Mental health care is a domain for which the impact seems to be relatively large. Dutch mental health care is in the process of being transformed from a homogeneous, regionally organised, integrated mental health care system, financed by a single social insurance, to a more heterogeneous working field, financed through several sources and subject to market forces. Stakeholders in Dutch mental health care welcome new possibilities this presents for providers, but concerns are expressed about the consequences of these changes for the quality and comprehensiveness of long term (community) care and for the sustainability of the mental health care system as a whole.

Keywords: Mental Health Care; Financing; Health Insurance System; Deinstitutionalisation Policy; the Netherlands

Recent studies, including those of the Mental Health Economics European Network, have shown that there are two dominant trends in mental health care financing in Europe. The first is a partial shift of funding to the social care and housing sectors. The second is a liberalisation of the health care sector and of health care financing as a whole.^{1,2,3}

Specific to the current changes in Dutch mental health care is that the first trend – the transfer of mental health care funds to non-health care domains – only takes place at a very limited level. To a much greater extent, Dutch mental health has become subject to a broader liberalisation process taking place within the health care sector.

Health and social care financing

Since 2007 health and social care in the Netherlands have been funded through three financing systems (Box 1). The first, the Health Insurance Act (ZVW or Zorgverzekeringswet) covers basic, essential health care. The ZVW was introduced in 2006 and replaced several previous health care insurance systems. The ZVW is the main vehicle for the liberalisation of health care in the Netherlands. It places a strong emphasis on market competition between insurers, and between health care providers. Under the new legislation all citizens are obliged to

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Box 1: Mechanisms for financing health and social care in the Netherlands from 2007

A new Health Insurance Act (ZVW)	Covering basic, essential health care; characterised by a central role for private insurers, and a competitive market.
A new Social Support Act (WMO)	Covering a broad range of social care domains; characterised by a central, autonomous role for local government, and the absence of individual entitlements or earmarked budgets.
The longstanding Special Medical Expenses Act (AWBZ)	Covering care for older people and those with physical disabilities, and until recently most care for people with mental health problems; characterised by well-defined entitlements, little competitiveness, and an administrative role for regional AWBZ offices.

purchase health insurance for basic health services. Consumers are free to choose any health insurer. Health insurers in their turn are expected to compete for clients on the basis of their premium rates and the quality of contracted providers. Health care providers are expected to compete for contracts with insurers on the basis of the price and quality of their services.⁴

The second financing system is the Social Support Act (WMO or *Wet Maatschappelijke Ondersteuning*) covering a broad range of social care domains, such as household support, youth centres, sheltered accommodation and special transportation facilities for people with physical disabilities. The WMO was introduced in 2007, one year after the implementation of the new health insurance legislation. In this new WMO system, several previous social care laws have been brought together. Under the WMO, local governments are the administrators of budgets and have considerable autonomy in deciding how to spend these. Budgets in the WMO are not earmarked and there are no individual entitlements. The responsibilities of the national government are mainly restricted to decisions concerning the total, national budget for the WMO.

The third financing system for health care and social care in the Netherlands is the Special Medical Expenses Act (AWBZ or *Algemene Wet Bijzondere Ziektekosten*) covering care for older people, people with disabilities and, until recently, most of the care for people with mental health problems. The AWBZ is the oldest of the three financing systems. It was introduced in 1968. The AWBZ is a relatively solid social insurance, which places an emphasis on strong and precise entitlements to care for people with more severe or chronic

health problems or disabilities. Regional AWBZ offices are the administrators of the AWBZ. Unlike the WMO, these administrators perform their role within strict, nationally regulated procedures.

Costs, sustainability and market competition

The recent reforms in health care financing in the Netherlands are motivated by one principal objective: preserving the sustainability of the health care system, or to be more precise the wish to gain control over the rising costs of health care. The ZVW is, in fact, the result of a policy process that started around 1990. As a result of that process subsequent government advisory boards have placed considerable confidence in liberalisation as a means of reaching a more sustainable health care system. In line with these views, the current Dutch government places great confidence in the ZVW to achieve cost reduction and quality gains. The WMO is also viewed as an important means of enhancing the sustainability of the health care system, albeit in a different way to the ZVW. The WMO offers the national government the opportunity to control total budgets (whereas open-end financing would lack that opportunity), leaving it to independent local governments to make ends meet.

In short, at a national government level there is much confidence in the ZVW and the WMO. The concerns of the current government concentrate on the AWBZ. It is argued that the costs of the AWBZ are rising too rapidly. In addition, the AWBZ, with its solid entitlements, open-end financing and lack of market incentives, is seen as one of the principal threats to the sustainability of the health care system.

Some advisory boards have already argued for the abolition of the AWBZ, and the transfer of its most important elements to the ZVW and the WMO respectively. In fact, for some AWBZ-financed health care and social care services, these transfers have already taken place. These include the transfer of the majority of mental health care responsibilities in early 2008.

The financing of mental health care

Over a period of thirty years, the AWBZ had become the principal source of financing for almost the entire mental health care system in the Netherlands. During its early years, the AWBZ was mainly used to fund long term clinical care and long-stay facilities. In trying to reach a more uniform financing system, and to stimulate cooperation between inpatient and outpatient care, outpatient services were incorporated step by step into the AWBZ-system. Since the mid 1980s, inpatient and outpatient mental health facilities, including short term mental health services, have been fully financed by the AWBZ.

The AWBZ has played an important role in the development of the current mental health care system in the Netherlands. From a rather patchy network of local, regional and nationally financed facilities, each with its own historical background, methods, and client population, Dutch mental health care has grown over the past three decades into a relatively homogeneous, regionally organised, integrated health care system that is clearly delimited from other health care domains.

The fact that all mental health care services were grouped under one financing-system has facilitated this development. So did the fact that mental health care was covered by a separate and specific set of entitlements within the AWBZ. A national policy emphasising regional cooperation and integration of mental health care services, alongside the organisation of the administrative management of the AWBZ through the regional AWBZ offices, further enhanced the regional integration of mental health care. Ultimately, this integration process culminated in mergers between mental health care providers on a regional level. As a result, Dutch mental health care in 2006 was dominated by forty regionally operating mental health care providers, each providing the full scale of mental health interventions (clinical and non-clinical) for their respective regional client populations.

It may thus be concluded that the current constellation of mental health care in the Netherlands has largely been the result of a long lasting and deliberate national policy. The main objective of that policy could be described as the implementation of a solid, comprehensive, recognisable and accessible mental health care system. The AWBZ was used as an important vehicle to reach this objective.

Turning point

It is important to note that the gradual integration of the mental health care system over recent decades has not been without criticism, for example from client organisations and mental health care researchers. Some argued that the development of a homogeneous mental health care sector, clearly delineated from other domains, could hamper cooperation with other health and social sectors and the integration of mental health care services in other domains. It was asserted that mental health care might be at risk of becoming an inwardly oriented sector on its own, insufficiently responsive to developments and demands from the outside. It was also contended that the vested interests in the solidly organised mental health care sector hampered the deinstitutionalisation process and the reintegration of people with long term mental health problems into society.⁵

Until the beginning of this century, however, the positive elements of the system were considered by the national government to outweigh these concerns. Not only had mental health care grown into a recognisable and accessible health care sector, the integration of mental health care services also enhanced the comprehensiveness, continuity and coherence of mental health care, especially for people with long term mental health problems. While it was also acknowledged that deinstitutionalisation was not a speedy process, it was also argued that some substantial progress was made, be it at a cautious pace, in the development of community based services, housing facilities, and rehabilitation and vocational services for persons with long term mental health problems. All in all, none of the subsequent national governments felt a need for a substantial policy shift.

In 2003, that perspective drastically changed. Specifically, the installation of a new government proved to be a turning point for Dutch mental health care policy. In the process of preparing the ZVW and

the WMO laws, new policy papers were published on mental health care. These policy papers emphasised the disadvantages of a homogeneous mental health care sector, clearly delineated from other domains. Concerns were expressed about mental health care being run by providers that operated as regional monopolies, leaving no room for consumer choice. It was also stated, that the relatively risk-free financing position of mental health care providers in the AWBZ offered insufficient incentives for innovation. It was concluded that mental health care would be better off if it could benefit from both the new, competition-oriented ZVW and locally embedded WMO.⁶

New incentives and disincentives in the provision of mental health care

Preparations for the transfer of mental health financing were not complete until 2007. In early 2007 a relatively small percentage (about 3 %) was transferred to the WMO (subsidies on consumer run projects, mental disorder prevention actions and outreach programmes for people with mental health problems, such as the homeless). Subsequently in 2008, a much larger proportion of financing was transferred to the ZVW. As a consequence, the ZVW has become the main financing source for mental health care, covering about two thirds of expected total mental health care expenses. In particular, the ZVW covers all short-term inpatient and outpatient mental health care, and all long-term community mental health care. Ultimately, only long-term inpatient mental health care and institutional housing facilities remain within the AWBZ.

The impacts of these reforms in mental health care financing on the structure of mental health care in the Netherlands are twofold. First there is the transformation from one to (at least) three financing sources. This means that, from the financial perspective, mental health care can no longer be viewed as a single health care sector. As a matter of fact, mental health care as such is no longer a delimited domain for national policy. No single government agency any longer holds responsibility for the whole of mental health care. Responsibilities are spread over several departments, with each defining and implementing policies on the ZVW, the AWBZ and the WMO respectively.

Second, market competition is being rapidly introduced into a field that used to

be determined by relatively secure annual incomes and by efforts to enhance cooperation. Specifically, conditions are being created where mental health care providers can no longer depend on their dominance on a regional level, and where opportunities are rapidly growing for competition for market share in other regions.^{7,8}

In short, the incentives contained within the new financing structures seem to be leading Dutch mental health care into a transformation process from a relatively homogeneous, regionally organised, integrated mental health care system (with all its pros and cons) to a more heterogeneous working field, financed through several sources, and subject to market forces.

First signs of a new mental health care system

The changes in mental health care financing are still very fresh and the exact consequences have yet to be fully grasped. Still, the first signs of these consequences can be gleaned from the way mental health care providers have so far anticipated the new financing system and from the growing discussion on the future of mental health care in the Netherlands.

The first signs from the mental health care field itself indicate that providers have already begun competing with each other for market share in the provision of short-term mental health care for people with mild mental health problems.

Some providers have begun developing facilities in the territory of their former colleague providers – now competitors. Marketing is a rapidly emerging activity in mental health care; new 'brands' for short-term care are emerging; and some providers are actively beginning to explore new niches in the market. In efforts to further ensure a solid market position, mergers are now taking place on an almost monthly basis.

Meanwhile, the regional organisation of the mental health care system is losing its dominance. Large, nationally operating providers are emerging alongside small, specialised, partially commercial mental health care providers. Initial findings also suggest that local governments are not always aware of their new (WMO) responsibilities for people with mental health problems.⁹

The new financing system has also generated debate about the future of mental health care in the Netherlands. In these discussions many welcome the new

opportunities in terms of the diversification of care products, the emergence of new providers and the supposedly growing possibilities for consumer choice.

But there are also discussions on the risks of the new system, in particular those concerning the quality of care for people with more severe and/or chronic mental health problems. Although there are as yet no solid empirical data to support these views, there are concerns that people with severe mental health problems may become unattractive (costly) clients for insurers. The new financing system might then encourage insurers to disinvest in good long-term community care.

There is also concern about the dispersion of responsibilities. Some fear that the new system carries incentives for local governments and insurers to shift the responsibility between each other for the financing of community support and rehabilitation and vocational services. There is also concern that local governments and insurers will try to shift patients from WMO and ZVW financed services back to long term inpatient facilities, financed by the AWBZ.⁹ In particular, many mental health prevention programmes and consumer run projects have been forced to end their activities, as they are not viewed as priorities by local governments.

In short, the first signs of the consequences of the new financing system for mental health care indicate a growing dynamic in the provision of short term mental health care services and in the market positioning of providers. Clearly at the same time, there are increasing concerns about the potential consequences for the sustainability of long-term, community mental health care services.

Conclusion

The changes in mental health care financing in the Netherlands are still very new. The real impact will become clear over the coming years. For the time being it seems safe to conclude that, in the slipstream of a broader liberalisation process of health care in the Netherlands, Dutch mental health care has entered an important transformation process. First impressions indicate that the new system has generated incentives for diversification and growth of short term mental health care, and for strategic manoeuvring of mental health care providers to strengthen their market position. Early indications also raise questions as to how these changes could facilitate the attainment of

national and international long term mental health care policy goals that have been set out in recent decades: deinstitutionalisation coupled with the development of community care and the enhancement of social inclusion of people with severe mental health problems. In fact, it is unclear what value is still attached to these goals by the current Dutch government.

These impressions lead back to the main objective of the current health care reforms: the sustainability of the health care system. The supposed cost-reducing mechanisms of the new financing system might require time to show and prove themselves. In addition, it is important to be alert to two possible risks. The first may be accelerating growth of (mental) health care, as a result of incentives within the competitive market system for providers to attract (new) clients. Referring to psychiatric epidemiological data, mental health care providers suggest that there is still a huge reservoir of untreated psychiatric disorders. Some have now started to search more actively for these potential new clients. The second risk might be in a stagnation of the development of rehabilitation and vocational services for people with long term mental health problems, resulting in less participation and greater costs both in terms of social welfare benefits and impacts on other social care domains. If these risks are borne out, what has been intended to be a means to preserve sustainability by reducing costs per product, might then threaten that sustainability by resulting in growing mental health care consumption and in additional costs to other publicly financed domains.

At this moment, however, the speed and the magnitude of change in mental health care financing, and the dispersion of responsibilities, mainly seem to lead to feelings of uncertainty about the future and to a sense of lack of direction for mental health care in the Netherlands. For these and the above reasons it would be desirable for these changes in mental health care financing to be accompanied by a new coordinated national mental health care policy, emphasising social inclusion and the full participation of people with mental health problems.

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Devolution and health policy in the UK

Scott L Greer

Summary: The United Kingdom has not one, but four health systems, and they correspond to its four different political systems. Northern Ireland, Scotland, and Wales each have an autonomous legislature that makes health policy while the UK government, somewhat oddly, directly runs England's National Health Service. Each political system has its own party politics and influential policy communities, and they therefore adopt divergent policies in spite of similar baselines and public preferences. Many of their future problems, in fact, might come from the UK's poorly defined rules for organising their interactions.

Keywords: England, Scotland, Wales, Northern Ireland, UK, Health Policy

It was at a private seminar in Edinburgh in 2005, and only after a long day of worthy UK-German comparisons, that a Scottish journalist saw the point that had eluded the speakers. Addressing the Germans just before dinner he said, "I get it. You think that decentralisation is all about doing the same thing, but with slight local modifications. We British think it's about doing different things!"

That journalist was right. The United Kingdom has had four politically autonomous health systems since 1998, with substantial autonomy and developing policy differences. It built them on a legacy of territorial divergence that existed before devolution – Northern Ireland, Scotland, and Wales had slightly different policies administered by their own health departments despite the overall unity of the UK government. The pressure to match such 'administrative devolution' with 'political devolution', i.e. elected governments, came about because of a will to do things differently: a will among Northern Ireland, Scottish, and Welsh political elites to have distinctive health and other policies; a shared will of their leading parties not to

experience the kinds of policies that UK governments elected with English votes imposed on them under the administrations of Margaret Thatcher and John Major; and a shared will among elites in Britain to quarantine themselves from the sectarianism of Northern Ireland's politics.

So eager were the framers of decentralisation – 'devolution' – to safeguard Scottish and Welsh political autonomy, and to quarantine Northern Ireland, that they created an extraordinarily loose settlement for devolution and one that even they now admit was not thought through.¹ The UK, unlike other decentralised and federal countries in Europe, does not have a shared statement of values or quality requirements. England, Scotland or Wales could abolish their National Health Service tomorrow – in fact, the only constraints on doing so would come from EU and European human rights law. The UK does not have shared data requirements or a shared basket of services or any mechanism to produce them. Financing is not just decoupled from any specific services; it is also allocated by the UK government through a formula with no solid legal basis.

At the same time, there are powerful forces creating policy divergence in the UK. First and foremost, each part of the UK has a different political party system. In Scotland and Wales, the Conservatives are a marginal force. The Labour party does

not just contend with the Conservatives in England, who get most of the press; it also must struggle for power and votes with the nationalists of Scotland and Wales. And at the moment those nationalist parties are doing very well; Plaid Cymru the Welsh nationalists are in coalition with Labour, and the Scottish National Party governs Scotland. The English Conservatives are to the right of Labour and never seem quite able to convince the electorate that they really value the NHS model; the SNP and Plaid Cymru are to the left of Labour and accuse it of faithlessness to the NHS.

As a result of these different party politics, health ministers – who are creatures of party politics – make systematically different decisions. They are aided by the fact that the health policy communities of the four systems are very different, with different actors, taboos, social networks and educational backgrounds. Contrast the omnipresent Scottish doctors, Welsh local government, and the English affection for professional (and even North American or Australian) management ideas.

Politicians in the four systems need distinctive ideas, and their policy communities are ready to supply them. There is some highly visible divergence: Scotland provides universal free long-term personal care for older people, Wales does not charge for prescriptions, and England has highly autonomous 'foundation hospitals'.

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Some are more nebulous – Wales tried hard to improve public health outcomes.

There are indirect distinctions as well; with four different ministers, four different budgets, and four different organisational structures, the four health systems produce different outcomes measured in hospital stays or patient outcomes (sadly, using four different kinds of data, so comparison is hard).^{2,3} Very broadly, the English system relies on introducing ‘contestability’, to force former monopoly health care providers to compete;⁴ Scotland has opted for reliance on professionals, less management, and partnership;^{5,6} and Wales experimented with local work on the wider determinants of health and on local accountability,⁷ although its new government is advancing reorganisation that would eliminate much of the connection of health services with local government. Northern Ireland, where democratic politics fails to provide much accountability for public services, is very stable because politicians are not typically elected on platforms remotely connected with health policy.^{8,9}

The loose, but fragile, institutional structure permits this devolution and the different politics provide the energy driving health policy in four different directions. The result is a fragile divergence machine, both capable of creating a remarkable amount of difference in ten years of devolution, but also easy to break because of its weak institutional base.¹⁰ It produces divergence despite the great difficulty analysts have in finding public appetite for divergence: the citizens of all four parts of the UK, when asked, think that social benefits should be the same across the whole state, and support the same (high) levels.¹¹ But politics, of course, often delivers something different from what citizens want.

Fragility of the divergence machine

Nothing was likely to break the fragile divergence machine in its first nine years because Labour was in office, solely or in coalition, across most of the UK, and its politicians had both the incentives, the internal hierarchies, and the back channels to sort out disputes without them becoming public. The exception was the Northern Ireland Executive, where the local parties intermittently held power but were too immersed in their peace process and too underinvested in health policy expertise to have many opinions. That is different now. The Labour Party is in

trouble in the UK government (where English voters are dominant), is out of office in Scotland, and is in coalition with nationalists in Wales who are unimpressed by both English market experiments and the performance of the existing – Labour-oriented – Welsh health policy establishment.

These changes in party politics revealed weak points of the UK settlement that academics had spelled out before.¹² The set of issues set out below should not surprise those familiar with German, Swiss, or Italian health policy, let alone the situation in fractious Belgium and Spain.

Finance

Northern Ireland, Scotland and Wales receive block grants from the UK government that they can use to spend as they like and have minimal taxing powers. Not only does this reduce their accountability to their citizens (since they do not raise what they spend); it also gives tremendous power to the UK government. This is exacerbated by the peculiar nature of the ‘Barnett formula’ which allocates new spending on a strict per-capita basis without sensitivity to need. This leaves English per-capita spending lower than that of devolved administrations.¹³

Quality standards and coverage

The UK devolution settlement has no shared values, standards, or goals built in. It would be a constitutional challenge to create them. This is unfortunate for Prime Minister Gordon Brown, whose speeches about “Britishness” incessantly invoke “the” NHS (which has never existed in law), along with the BBC, as institutions that justify the continued existence of the UK.

Weakly institutionalised intergovernmental relations

Intergovernmental relations are a blind spot in health policy debates, despite an importance that no sensible analyst of health policy in Spain, Canada, Australia, Germany, or many other countries, would deny. Demographics, diseases, or population characteristics do not matter if the governments cannot arrange the laws, financing, and technical skills to make policy. In the UK, the problem is that the devolution settlement scarcely recognises shared interests, whether in communicable disease control¹⁴ or most other policy areas.¹⁵ Governments are flying blind, relying on weak law and personal connections that are becoming rarer and rarer.

EU health policy

The UK devolution law is clear: the UK government is the member state, not Northern Ireland, Scotland, or Wales, and while it should take their views into account, it need not adopt them.¹⁶ Scotland and Wales have become influential regional governments in the EU partly because they worked so well with the UK, something that depends on a level of friendship that is already eroding.¹⁷ If the UK loses a case against them in the European Court of Justice, the UK pays, but can subsequently claw back the damages from their budgets (and because of that it can intervene to threaten them when they pursue policies it thinks might violate EU law).

Public acceptance of divergent policy

Do the public, as patients or citizens, accept divergence? What parts of the UK’s public accept what level of divergence? And will politicians make a political point of it? The press in each polity tends to present the issue in terms of unfairness measured in spending or services, but there is also a level of unfairness, often inherited from before devolution, in outcomes. Some newspapers (the *Daily Mail*, the *Sun*) have already been using the inflammatory headline ‘Medical Apartheid’ to discuss cases in which devolved health services offer better services than the English NHS because they claim better per-capita funding.

All of these issues could create a political crisis or, more likely, impinge on the devolved governments’ ability to pursue divergent policies. They create incentives for politicians to create crises and blame each other, and leave the UK with few clear mechanisms to resolve disputes.

Divergent trajectories?

Very little public opinion in the UK suggests support for divergent health policies or outcomes (though, as many analysts have pointed out, there has always been a high degree of local variation in the actual performance and even services of the NHS in any part of the UK despite public support for unanimity).¹⁸ So if public opinion polls generally show desire for the same (high) levels of provision, and little support for the idea of divergence in principle, should we expect learning and convergence rather than the divergence predicted by political analysis?

Convergence seems most likely in outcomes that matter greatly to the public, such as waiting or ambulance response

times (where England has hit its low target on elective waits, while targets are easier and less met elsewhere).¹⁹ Welsh voters might be alarmed by their health system, with statistics such as the remarkable 2004 survey finding that only 31% of the Welsh health service leadership said they would want themselves or a loved one to be treated in Wales.²⁰ It is possible to argue that we have already seen convergence, with limited 'patient choice' schemes across the UK and an emphasis on cutting patient waiting times in Scotland and Wales. In this reading, devolution would mean that Northern Irish, Welsh, and possibly Scottish voters would be able to use the new democratic accountability of their politicians to force standards up. It might even mean that the four governments would adopt each others' successful policy innovations (an argument made most often, in my interviews and experience, by English policymakers).

But the pressures for convergence, or even the pressures for convergence on topics that matter to the public such as waiting times, are often surprisingly weak. Public opinion might suggest a focus on providing the kind of (local, respectful, quality) care that most polls suggest voters want, but many other things shape political agendas, and they generally have more to do with party politics and policy communities than difficult-to-measure and difficult-to-mobilise public preferences.

The reasons to expect a continued level of divergence, on the current coherent trajectories, lie mostly in the strategic situations of political parties. Even if Scotland is now governed by the (minority) government of the nationalist Scottish National Party, the swing voters who decide elections remain much the same in Scotland, and Scottish politics reasonably caters to them. Even if England is currently governed by Labour, the presence of a large Conservative opposition means that the government must cater to Conservative-leaning voters. So those who expected radical change with the devolved elections of 2007 were disappointed; there is a limit to how much even new parties will change policies.

Health system challenges also limit the radicalism of governments. Health services are both easy and hard to change: it is easy for governments to create a blizzard of policies, but it is also very hard to change their underlying nature. English policymakers have had trouble harnessing market dynamics, let alone creating something resembling a market. And that is

despite unprecedented injections of money and political effort.

Welsh efforts to turn the focus of health policy from health care to health have also run into setbacks since most of the policies that improve population health and reduce inequalities are in the hands of other ministers (as with education or transport) or are in the hands of the UK government (as with taxes and benefits). Both English and Welsh health policy has drawn back from the heights of innovation, while the less novel Scottish system, which harkens back to the NHS systems of 1974–1983, is much more politically stable – and that is probably because it is less of a challenge to professional and traditional ways of working in the NHS systems.

So if Scottish, or Welsh, or UK governments of any colour and their oppositions pursue much the same voters and the same distinctive Scottish, Welsh, or English political agendas, we can expect further divergence as day to day policies go in different directions. But as they, together with the parties in the Northern Ireland Executive, are constrained by the fragile system of intergovernmental relations and their various historic legacies, we can also expect that all four of them will continue to find that divergent incremental change is far easier than systemic reform.

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Engagement with Russia – not isolation – in the health sector

Edward J Burger and E Wayne Merry

Summary: The health crisis in Russia is of major importance to that country and to the West. The crisis is real and will not abate without action. The outside world has focused on infectious diseases in Russia, especially tuberculosis and HIV/AIDS. However, the biggest killer in Russia, by far, is cardiovascular and cerebrovascular disease, especially among men in their most productive years. There exist proven solutions for these killers and some successful experience in cooperation in the health sector. This is a very good place for the new Russian and American administrations to start in repairing the relationship, in both our interests. There is a tangible contribution that can be made to Russian health and, ultimately, to the devastating demographic decline in Russia. We need to reverse the current trend toward re-isolation of Russia. Medical and scientific cooperation has an exceptional opportunity to contribute to re-engagement.

Key words: Russia, demography, cardiovascular disease, foreign policy

Health is in bad shape in Russia

A decade and a half after the breakup of the Soviet Union, the Russian Federation continues to exhibit critical health problems. Excess or premature mortality and decreased fertility have produced a population decline of 600,000 to 800,000 per year net of any in-migration. The impact of excess mortality is visited particularly on men and, importantly, on men in their most productive years. Male life expectancy from birth, which began to decline in the late 1960s, reached a low of 57 years in 1995 and generally held steady at 58 years over the next decade.^{1,2} The two years, 2006–2007, saw a modest increase in life expectancy for men and women but this did not match the magnitude of the declines of the 1990s. Further, it is not clear that these reversals of prior trends will be sustained.³

Russia's population in January 1992 was of the order of 148.7 million. On 1 December 2005, the population was reported as 142.8 million citizens, reflecting an annual loss

rate of 0.3%.¹ The underlying causes are straightforward enough – a disproportion of deaths over births. Reduced fertility and population decline are not unknown in Western Europe or Japan. However, in Italy, there are 103 deaths for every 100 births, while in Russia the corresponding figures are 170 deaths for every 100 births. The Russian experience has been described as being without precedent outside of periods of war and famine.⁴

The difference in life expectancy from birth for males and females is fourteen years. The principal contributor to excess mortality is acute, life-threatening complications of underlying cardiovascular and cerebrovascular disease – heart attacks and stroke. Cardiovascular mortality for males in Russia aged 25–64 is four times that in Ireland, Western Europe's highest level.⁵ The second-ranked contributor is violence – accidents, poisoning and suicide. For men under 65, Russia's death rate from injury and poisoning is four times that of Finland, the worst record among EU nations, and over twelve times that of the UK.⁴ A recent United Nations Development Programme report noted a trend of increasing incidence of 'external' or violence-related causes of mortality reflecting poverty and marginalised younger members of the population.³

The pattern of high, age-standardised male

mortality is relatively uniform among the 84 components of the Russian Federation, with the exception of two regions of the Caucasus – Dagestan and Ingushetia. In addition, these two regions plus fourteen others along the southern tier of the country are the only components of the Federation exhibiting a positive natural increase in population.

The epidemiological basis for the record of excess mortality, and acute complications of chronic, non-communicable disease, has important implications for appropriate action. Most important, this record of cardiovascular mortality is amenable to medical and public health intervention. Cardiovascular mortality is common throughout the world and is an increasingly prominent cause of death in transition economies. The two most important risk factors are cigarette smoking and undetected and, therefore, untreated vascular hypertension. Recognition and appropriate treatment of hypertension in the US, beginning in the 1960s, and utilising very simple medications (diuretics), succeeded in reducing cardiovascular mortality by over 60% in three decades. The untreated prevalence of hypertension in Russia affects approximately 27% of the adult population, similar to that in the US. However, unlike the US where it is estimated that 60% of cases of hypertension

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are recognised and placed under treatment, only 8% are in Russia.⁵

There has been significant foreign attention in recent years to infectious disease in Russia, especially tuberculosis (TB) and HIV/AIDS. The burden of these diseases is certainly very important. TB historically has been considered a disease of older people, but in Russia, the mean age of patients began to drop in the 1990s. By 1994, 40% of TB deaths occurred among patients younger than 39.⁶ The disease now disproportionately affects young adults, particularly men.⁷ All three disease entities, myocardial infarctions and stroke, TB and HIV/AIDS, have their greatest impact on men in their most productive years. However, cardiovascular mortality in Russia overwhelms that from the other two diseases combined^{8,9} – any serious effort to arrest the demographic decline in Russia demands a concentrated attack on this disease.

The Russian health and mortality record is paradoxical in that it is generally believed an improving economy brings with it commensurate improvement in the social and health status of its citizenry.¹⁰ The level of economic activity has risen at annual rates of 6% to 8% over the past four years despite the continued drop in population. Despite these indices of economic progress, they have not caused ‘all boats to rise’. Russia has shown a slight gain in fertility and a modest decrease in infant mortality.¹¹ However, the record of markedly depressed early adult mortality, while modulated slightly, remains exceptionally high, notably for working-age men.^{3,4}

Consequences of continuation of the present course

If Russia is unable to alter the present demographic decline, the consequences are dire. The US Census Bureau's ‘optimistic’ projection is for a reduction of ten million in the Russian population between 2000 and 2025. The United Nations Population Division ‘medium variant’ projection, suggested a drop of more than twenty-one million over the same period.⁴ A recent UNDP review of demographic trends in Russia predicted a need for 22 million additional workers by 2023.⁴ In-migration of Russians to the Russian Federation from other parts of the Former Soviet Union, the hoped-for safety valve to counter the large negative natural increase at home, has slowed to a trickle. At the same time, out-migration of Russians continues. Internal migrations are also altering the country's

demographics, most dramatically in the Russian Far East with a loss of population at a rate much higher than that experienced by the nation as a whole.

By 2015, the cohort of eighteen year old men will number 600,000 to 650,000 and be insufficient both to serve in the military ranks and to enter university at present levels.¹² Indeed, today's conscription rates would exceed the total cohort of eighteen year old men at that time. These conscription rates will increasingly conflict with the imperative that many young men pursue higher education.

A reduction in the flow of students into higher education will threaten the ability of the nation to reach its full economic potential. The current economic base is heavily dependent on a single sector – extractable resources, most notably oil and gas. For 2003, the US Central Intelligence Agency estimated that over 80% of Russian exports were derived from sales of energy resources, timber and metals. Thus, the overwhelming majority of the Russian work force contributes only 20% to the nation's export earnings. In Ireland, the comparable value of non-resource exports was about 150 times as much on a per capita basis. Global competition increasingly requires higher value-added contributions which necessitate an educated work force. Thus, Russia's economy cannot diversify beyond the limitations of its current commodity export structure under the projected demographic constraints.

Continued improvement of the economy will depend on both the number of workers available and the quality and health of that work force, both of which are currently compromised. The World Bank estimates that the combined cost to Russia of deaths from heart disease, stroke and diabetes on labour supplies and savings at \$11.1 billion and proposed that that figure could rise to \$66.4 billion in 2015, ten times the corresponding estimate for the UK.⁹ Translating these losses into a percentage reduction of gross domestic product (GDP) would mean a reduction of 1% in 2005 rising to over 5% by 2015.⁹

A significant level of immigration of non-Russians is required to compensate for declining population numbers and to meet economic and security challenges. In fact, that trend is already underway. Russian oil and gas companies employ large numbers of non-citizen workers, especially from Central Asia. In addition, even without

immigration, the Russian population will become decreasingly Russian, Slavic and Orthodox due to a combination of continuing out-migration of highly educated Russians and inward migration of low wage personnel from elsewhere in the Commonwealth of Independent States and beyond.¹²

A federal programme was announced to begin in 2007 to encourage immigration of up to one million individuals to help compensate for Russia's demographic loss.¹³ The programme will cover the cost of resettling immigrants, provide loans and offer unemployment benefits for up to six months. The programme spokesman announced that he expected most immigrants to come from countries with a “...large workforce but unstable economies.” In a similar vein, in November 2003, the Federation government issued rules that made it possible for foreigners to serve in the Red Army and ultimately earn citizenship for their duty¹⁴ (although, reportedly, only 300 foreign workers are currently serving in the Russian military).

Immigration, to a great extent, implies immigration by individuals from Muslim Central Asia and China in the Far East. The number of Chinese who have actually migrated to Russia appears to be relatively small, although fear of that migratory trend is very high. Immigration of Muslims is more complicated. Ethnic Muslims already constitute just over 10% of the total population and 9.5% of the male population. The percentage of Muslims of conscription age is slightly higher (10.07%) and promises to rise further at a time when the absolute numbers of 18-year old males will be unusually low.

Importantly, Muslims in Russia tend to have a higher fertility rate and greater longevity than Slavic Russians. Those living in the predominately Muslim regions of the Southern Federal District are more likely to have been in higher education compared with Russian males in general but they are more likely to be unemployed.¹⁵ By some estimates, 14 to 23 million Muslims live in Russia¹⁶ and Moscow already contains two and a half to three million Muslims. In 2004, 45% of live births in Moscow were to parents of ethnic Muslim origin.¹⁷ In the long run, diversity is desirable. In the immediate future, and in the face of economic slow down, the implications for social instability within the multi-ethnic and multi-

confessional Russian Federation are feared to be adverse and serious.

The trend toward re-isolation. The case for engagement

Alexei Arbatov, Scholar-in-Residence, Carnegie Moscow Center, in a thoughtful disquisition on US-Russian relations, warns of the possibility of Russia's moving toward a "...neo-isolationist foreign policy focusing only on ensuing transient and acceptable prices for oil and gas exports, and selling weapons, nuclear materials and nuclear technology to any prospective buyer."¹⁸ There is no argument that US-Russian relations have deteriorated over the past few years. A recent report of a Commission on Smart Power by the Center for Strategic and International Studies labelled US-Russian relations "chillier than they have been at any time since the end of the Cold War."¹⁹ Dmitri Trenin of the Moscow Carnegie Center has described the current atmosphere as "toxic."²⁰

Isolation, of course, was a feature of most of Tsarist Russia's history. Seventy years of Communism furthered the trend. Yet, it is precisely this aspect of isolation which is in the interest of neither Russia nor the West. Former US Senator Gary Hart, wrote that "an isolated, anti-democratic Russia increases our insecurity. Russia's development as a market democracy will best be achieved by engagement, not rejection."²¹

The health sector, as singled out by the Commission on Smart Power, presents particular opportunities for cooperation. This focus on health properly complements other key elements of foreign policy, such as economic development and security, and merits a similar level of attention. As a report from the Council on Foreign Relations noted, the rationale for this position includes a combination of both humanitarian and good leadership qualities, on the one hand, and self-interests on the other.²²

We are inevitably anxious about the spectre of infectious disease such as HIV/AIDS and TB, including drug-resistant TB, intruding on our shores. The fear has justification in the face of epidemics abroad, the mobility of peoples and the use of rapid and dense mass transportation. For example, the transitory epidemic of TB in New York City fifteen years ago, and its lower but still evident prevalence there now, are in part attributable to travel and immigration from high

TB areas of the former Soviet republics.

However, our broader self-interest derives from the recognised relationship between social well being and health, on the one hand, and political stability and economic development on the other. Health both influences and is affected by economic development. Health is both an economic input and an output. A high prevalence of disease and disability, coupled with reduced longevity, compromises economic productivity and the contribution of the workforce to the economy through labour shortages and absenteeism.

What is the interest of the West?

In the views of these authors, we in the West have a self-evident interest in the preservation of a stable Russia and in the promotion of a healthy and prosperous Russian nation. Unfortunately, the legacy of Western assistance to post-Soviet Russia is very mixed. Far too many programmes and Western participants approached Russia as a laboratory for their social and economic theories, knew little about the country or were unwilling to learn, and dealt with Russian counterparts on a basis of condescension and sermonising. Many of those programmes were focused inappropriately on economics or on societal transformation.

In contrast, an early (1992) well-conceived and successful programme was the Hospital Partnership Programme which linked twenty-six US institutions and a corresponding number of medical centres in the Former Soviet republics. Unfortunately, the programme was later substantially altered from its original conception. What followed was a very weak, discontinuous effort characterised by short-term, ever-changing goals. For the past fifteen years, there has been a lack of any coherent strategy for health cooperation and assistance with Russia. That lack of coherent direction has led to a large universe of privately supported and initiated projects, led by a variety of non-governmental and faith based groups. All of these have been well intended but have varied in quality and been episodic in character.

Precedents from the past – the example of Latin America

There are some highly successful examples of past initiatives in which health has been used explicitly as an instrument of foreign policy. In 1942, Nelson Rockefeller, impressed with the importance of health as a vital element in Latin American social

and economic development, and with the strong support of President Roosevelt, established a quasi-governmental corporation, the Institute for Inter-American Affairs, devoted to health and medicine assistance for eighteen Latin American nations. The extra-governmental form was chosen explicitly to allow for flexibility, to encourage contributions by professionals from the academic and foundation communities (especially the Rockefeller Foundation) and to avoid the burdensome restrictions of normal US governmental regulations. The US committed itself to a long-term project with a set level of funding. The understanding in all cases was that the host Latin American country would eventually assume 100% of the cost.

The programme was extremely successful. From the beginning, it worked closely with host governments. It enjoyed a substantial continuity and longevity, coming to an end only in 1958. The programme, in collaboration with the Rockefeller Foundation, built hospitals, nursing schools, health clinics, supported training programmes for visiting nurses and health education programmes for the general public. Among its most important characteristics were coherence of effort, the continuity of long-term dedication, a strong element of professionalism and a sense of partnership and cooperation rather than a donor-recipient relationship.²³

The scale and creativity and the resultant quality of professional contributions involved contrasts sharply with the present portfolio of foreign assistance programmes for health in Russia. Fortunately, there is a legacy to build on. Some of the most consequential interactions to date have been in the fields of science and medicine. Borrowing from past experience, we should emphasise the key role of professional exchanges. These not only contribute to social and health improvement but represent highly effective vehicles for public diplomacy and soft power. However, the key is partnership, not assistance. During the course of the earliest exploratory mission of American medical professionals to the former Soviet republics following the breakup of the Soviet Union, a visiting delegation was offered the advice, "...diminish foreign assistance but help us help ourselves."²⁴

Some principles for effective cooperation

A successful cooperative health programme should focus on projects which promise

real benefits to health. In practice, this means a focus on those diseases which are the most prominent contributors to Russian premature mortality – heart attacks and stroke. The death rate from cardiovascular disease is more than ten times greater than from AIDS, TB and malaria combined.²⁵ As noted above, premature deaths from these causes are preventable and trends can be reversed. A second important principle is continuity of effort. To be effective medically and to earn the collaboration of the professional medical community in Russia requires investment sustained over an appropriately long period of time without abrupt changes in direction and priority.

A third important principle is insistence on professionalism in the design and performance of cooperative efforts. For a number of reasons, USAID in recent years has turned to large private contractors to undertake development and assistance projects. While this has, perhaps, added administrative and economic efficiency to assistance efforts, those projects designed to improve health have often lacked the knowledge and talent of professional medical institutions and individuals who are recognised for their scientific prowess and know the territory. Susan Raymond, currently Executive Vice President to the company Change Our World Inc., which provides advice to global non-governmental organisations and foundations, in an advisory report to the Administrator of USAID a few years back, emphasised this point in a strongly worded report. She recommended "...a strategy that drives away from reliance on third party contractors for portfolio development, and toward institutions that share the problems and potential gains from addressing problems/opportunities (for example, professional associations)".²⁶

The vast majority of the Russian medical profession was isolated from Western medicine and medical science for seventy years. The legacy of this professional isolation itself presents an opportunity to share knowledge, skills and experience with colleagues throughout the world. Programmes such as the ten-year Eurasian Medical Education Programme of the American College of Physicians have proven the effectiveness of professional medical education exchanges to increase the capacity of the Russian medical profession to prevent and manage serious disease. The investment is small but highly targeted and the leverage is large.

The opportunity may be now

Former President Putin highlighted Russia's demographic decline in successive speeches to the nation and Duma during his term in office.²⁷ In each instance, Putin used the weight of his office to emphasise the importance of the issue. He used phrases such as "...the most serious threat to the country..." and "...one of the most acute problems." From time to time, other Russian spokesmen have taken visible notice of demographic loss.²⁸ In September 2005, Sergei Mironov, Chairman of the upper house of the parliament, told a meeting of Russia's Life Party that "...from a demographic point of view, there is no great difference between the Civil War including collectivisation, the Great Fatherland War (World War II), and the end of the 20th century."

However, only recently has the 'warning from the top' been followed by tangible governmental actions and the allocation of new funds. In his 20 June 2006 address, President Putin announced a pro-natalist programme of subsidies to encourage child bearing.²⁷ Perhaps the most tangible proposal was the Kremlin's announcement in 2006 of a series of four 'national projects' devoted to improvements in health care, education, housing policy and agriculture.²⁹ The President announced the commitment of 195 billion roubles (\$6.9 billion) per year to the 'demographic project'.³⁰ Cardiovascular disease was the subject of prominent concern and, for the first time, the Russian Federation Ministry of Health and Social Development considered the issue of tobacco consumption in Russia.³¹ Perhaps most important was the appointment of Dmitri Medvedev, then Deputy Prime Minister and now President, as the overseer of these national projects.

The new opportunity for cooperation comes from these indications that Russia has begun to take the health and population problem seriously and from the approaching political changes in Washington and recent changes in Moscow. The 'honeymoon' period for the two new presidents will present opportunities to re-engage the troubled relationship. There is no better field for productive cooperation than health care. The American side should take the initiative, but we should seek projects and programmes marked by professionalism and collegial partnership, and move away from traditional foreign assistance whose hallmarks are 'donors' and 'recipients'.

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Health care and pharmaceutical policies in Turkey after 2003

Nebibe Varol and Omer Saka

Summary: The health care system in Turkey has been going through a series of crucial reforms in recent years. The most tangible steps in this reform process were launched after the Justice and Development Party (AKP) emerged as the ruling party in the elections of 2002. The EU accession and harmonisation process has also provided additional momentum for implementation of change in the health care system. This article assesses the extent to which actions to date are consistent with the objectives of the reform programme launched in 2003.

Keywords: Health System Reform, Pharmaceutical Policy, Turkey

The health care system in Turkey has been going through a series of crucial reforms in recent years. The most tangible steps in this reform process were launched after the Justice and Development Party (AKP) emerged as the ruling party in the elections of 2002. The EU accession and harmoni-

sation process has also provided additional momentum for implementation of change in the health care system. Thus one of the first political decisions the AKP took was to launch the Health Transformation Programme* (HTP) in 2003.

The overarching objectives of the transformation programme were firstly to reduce inequalities in access to health care within the country and secondly to narrow the gap in the utilisation and quality of health services observed in Turkey compared with other middle-income, as well as EU, countries.¹ The specific objec-

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* Also known as Health Transition Project

Box 1: Stated objectives of the 2003 Health Transformation Programme

Restructure the Ministry of Health to facilitate more effective stewardship and policy making

Establish a universal health insurance fund to ensure equity and access to health services

Reorganise health care provision so as to separate service delivery from financing in order to achieve a more efficient resource allocation

Introduce family medicine to integrate and streamline the delivery of primary care with inpatient care

Ensure financial and administrative autonomy for all hospitals to improve technical efficiency and strengthen management

Set up a fully computerised health and social care information system

Encourage the private sector to invest in the health care sector

Improve maternal and child health

Eliminate shortages of health personnel in areas earmarked as being priorities for development

tives of the HTP are outlined in Box 1.² The article assesses the extent to which actions to date are consistent with these stated objectives.

Restructuring of the MoH for effective stewardship

The main components of the reform agenda include restructuring of the Ministry of Health (MoH) to encourage decentralisation, establish monitoring and evaluation capacity and ensure the quality of health care services. The MoH has transferred responsibility to the provincial authorities on the opening and closure of pharmacies, as well as for the monitoring of marketing and consumption of pharmaceuticals. In addition, decisions regarding extra working hours and transfer of health personnel between provinces, and the career progression of health personnel according to performance criteria are also now to be taken at the provincial level. As yet however, the necessary legislative changes have not been completed.

In a related aspect of reform, the Directive on Institutional Performance and Quality Development has been issued and a Quality Coordination Unit established under the MoH as the responsible authority for quality management in hospitals and other institutions that provide health care. The performance of hospitals is now evaluated through inspections undertaken in accordance with this directive.³

Establishment of a Universal Health Insurance Fund

Another element of reform has been to support the establishment of a universal health insurance fund through the consolidation of different health insurance schemes* under one umbrella to ensure equity of access to services. The most important recent developments in Turkish social policy have been the enactment, despite much heated debate, of both a Social Security and General Health Insurance Law and Social Security Institution Law in 2006.⁴ The new system embraces all social groups, including individuals not formally employed, and aims to facilitate universal access to health care services. Different reimbursement mechanisms employed by different social security institutions have been replaced by one model following enactment of the General Health Insurance Scheme (GHIS) by the Turkish Parliament in 2006.

Since January 2007, no payment is required for primary health care services, even if an individual is not covered by a social security scheme. Rejections, due to different insurance or payment processes, have been eradicated for emergency admissions in all health care institutions.⁴ Individuals below the age of eighteen are

covered by the health insurance scheme free of charge. Considering the extent of child poverty in Turkey (according to the Turkish Statistical Institute approximately 5.7 million children under the age of fifteen were living in poverty in 2004), this provision is extremely significant in the context of the Turkish health care system.⁵

The Green Card Scheme, which helps cover health care costs for those living below a state determined poverty line, was extended in 2005 to cover all health care expenditure (previously outpatient care and prescriptions had been excluded) which facilitated the access of the poorest segments of the society to health care. Currently Green Card holders are fully covered, with the exception of a 20% co-payment for prescriptions. Access to medicines for SSK and Green Card beneficiaries has been improved by granting them the right to obtain medicines from all private pharmacies instead of the limited number of specified pharmacies that had provided this service in the past. Similarly, private hospitals can now be reimbursed for health care services provided to individuals covered by the public insurance scheme.

Reorganisation of health care service delivery

Reform measures have included the adoption of family medicine for the provision of outpatient or primary health care services, the integration and harmonisation of MoH and SSK hospitals, as well as the further development of services for the prevention and control of non-communicable diseases and the introduction of more effective maternal and child health interventions.

In November 2004, Parliament approved legislation to pilot a new family practitioner scheme. Implementation initially began in Düzce province, with the aim of extending the scheme to the whole country by 2008. Currently nine million people can avail themselves of the family practitioner scheme, which has been rolled out to the provinces of Eskişehir, Gümüşhane, Edirne, Bolu, Adıyaman, Elazığ, Denizli, Isparta, Samsun and İzmir. The introduction of the scheme has also been accompanied by a decrease in the number of patients presenting to secondary and tertiary care facilities. While the number of

* Social Insurance Organisation (SSK), the Government Employees Retirement Fund (GERF), the Social Insurance Agency of Merchants, Craftsmen and the Self-Employed (Bag-Kur) and Green Card Scheme.

contacts with primary care have increased by 37% from 1.7 to 2.3 million, referrals to hospital from primary care have also decreased.⁶ In addition, community health centres have also been established to further increase access to effective primary care services and monitor family practitioners. They also provide logistical free support for vaccination campaigns, as well as mother and child care and family planning services.

We have noted that all SSK and other public hospitals, previously not under the control of the MoH have now been transferred to the MoH. Thus the MoH is now the principal actor in health care provision followed by the university teaching hospitals. Another welcome improvement in legislation governing health care provision now permits state hospitals to use their own revenues to purchase selected services from private providers. This has resulted in a better use of already established but underutilised private hospital capacity. The relative workloads of the public and private health care facilities have also improved since private health care facilities now provide service to individuals covered by public insurance. More responsive management structures have also evolved as a result of the increased autonomy of public hospitals. One example of such managerial innovation that we can point to is the establishment of data processing infrastructures in most hospitals in recent years.

Performance-based additional payment to personnel from revolving funds

As part of the HTP objectives, performance indicators were developed and performance-based payment systems were established. Performance-based revolving fund payments which link the revenue of hospitals to the hospital personnel payment schemes have resulted in the voluntary extension of working hours by hospital personnel. Financial incentives have driven most specialists to close their private offices and start working only in hospitals, which in turn has relieved patient overload in hospitals. Such policies have increased the proportion of practitioners working full time in the hospital system from 11% in 2003 to 60% in 2007. The effectiveness of patient registration systems have also increased due to the introduction of the performance-based system. Currently all hospitals have established electronic database systems: before the reform process only 20% of hospitals had this capability.

Building a health information system

The Health Transformation Programme emphasised the need for better quality information to make sound health system policies and administrative decisions. The creation of health information systems requires both the integration of data obtained from different institutions and its packaging in a format amenable to use in decision making processes.

Institutions involved in providing health services, as well as data banks of physicians, international disease classifications, medicine and medical product codes have all been identified and/or harmonised. A system for the surveillance of personnel, material and financial sources (The Core Sources Management System) has been completed. A Family Medicine Information System has been implemented to store electronic patient record data in the provinces where the new primary health care system has already been rolled out. Moreover, in October 2007 all public hospitals adopted the Medula System, which will enable the creation of a health database to be used for health care data analysis.⁷ This is an integrated information system for the electronic collection of billing information from health care providers and payments to health care services by the Social Security Institution.* Efforts to determine further infrastructural needs related to the inclusion of all relevant actors in the health system are ongoing.

National pharmaceutical policy and efforts to establish evidence-based policies

Turkey has been criticised not only for its lack of transparency in pricing and reimbursement decisions, but also a lack of communication with the pharmaceutical industry.⁸ The price of pharmaceuticals used to be determined based on a cost-plus approach until 2004. Concerns regarding the rising share of pharmaceutical expenditures in total health care expenditures and pressure to contain public expenditure have resulted in revisions of pricing policy. The MoH Decree on Pricing of Medicinal Products for Human Use issued on 6 February 2004 introduced external reference pricing as the main price setting criterion. The price of new drugs will be set to the lowest price in a basket of reference countries (currently France, Italy, Greece, Spain and Portugal). The reference price system has also improved

transparency: reference groups are formed based on similar dosage, same active ingredient and same indication. Reimbursement levels are set at the lowest price in a reference group plus 22%.⁹

Pharmaceutical prices have been pushed down due to a combination of discounts effectively applied to approximately one thousand products, a reduction in value added tax from 18% to 8% for pharmaceuticals, and the increase in the negotiating power of the public insurance scheme as the sole buyer in the market. Turkey has had a unified reimbursement system since 2003 with a common positive list for all social security funds. Reimbursement is based on rules set out in the Budget Implementation Guidelines (BIG). The Reimbursement Commission, established in 2004, is the key body in the preparation of BIG reimbursement decisions and the inclusion of products on the positive list. The inclusion/exclusion criteria for the list are still not clear; budget impact has so far been the most influential criteria. A significant number of over the counter (OTC) products were excluded from the list after 2004; however, there are still a significant number of reimbursed OTC products which implies that, coupled with a better use of generics, they can generate additional savings.⁸

Legislation enacted by the Social Security Institution in 2007 stipulates the submission of an economic evaluation for all new pharmaceuticals requesting reimbursement. The main challenge of this development is the inadequacy of epidemiological and health care data in Turkey, as well as a limited capacity in skills needed to build and evaluate pharmacoeconomic models. Health economics 'know-how' in Turkey needs to be developed both in the private and the public sector. A database also needs to be created to provide access to information on the epidemiology of diseases, current treatment practices, the efficacy of treatment options and health care costs.¹⁰

Data exclusivity

New data exclusivity principles were introduced in 2005 as one of the steps on the path to eventual membership of the European Union. Data exclusivity applies for a period of six years following the first registration date within the EU Customs Union area and is valid provided that it is limited to the patent term. As part of EU

* The authority responsible for the social security provisions in Turkey.

accession, this data exclusivity period might be extended to the 8+2+1 principle for alignment with the EU.¹¹

Tackling counterfeit drugs and a Track and Trace System

Counterfeit drugs have remained a problematic issue in Turkey.⁷ A new Drug Track and Trace System (ITS-Ilac Takip Sistemi) has been implemented in Turkey to reduce the amount of counterfeit drugs in circulation. Tracking of individual drug packages has been mandatory since February 2008. According to the new regulations a Datamatrix barcode including information about the product code, serial number, order number, production date and expiry date must now be printed on drug packages, in addition to the already existing barcode requirements.¹²

Future outlook

The Health Transformation Programme and the EU accession process have been the major driving forces of health care reform since the beginning of the new millennium. Efforts have been focused on creating a purchaser-provider split, extending coverage to the whole population based on social insurance principles and organising primary care through family practitioners and autonomous hospitals.¹ There have been considerable changes in pricing and reimbursement policies to improve the objectivity and transparency of decisions. Pharmacoeconomic evaluations have been introduced as a new criterion in the reimbursement process. The need for sound information, robust data collection and the development of human capacity for health economic evaluation stand out as major hurdles to be overcome in the quest for sound evidence-based policy making.

What are the next steps in the reform process? A number of key developments can be identified in the latest programme for government published in September 2007.¹³ These include the transformation of the Refik Saydam Hygiene Centre (The School of Public Health) which carries out research on health care systems, health economics and health management into the Turkish National Institute of Health.

An independent 'National Pharmaceutical and Medical Equipment Agency' will also be established. This agency will develop and audit the necessary guidelines for the production (including ingredients), import and export of pharmaceutical products,

cosmetics and medical devices. It will be charged with ensuring safety, effectiveness, quality and compliance with standards in providing access to these products.

The family practitioner scheme will be extended to the whole country in cooperation with Ministry of Finance, Social Security Institution, and local administrations. In this context, valuable experience with the current family practitioner practices will be drawn upon to enact the necessary legislation for the implementation of a nationwide scheme.¹⁴ The governmental health programme also affirms a commitment to strengthen efforts to promote maternal and child health and build national programmes to combat non-communicable diseases.

Finally, public hospital unions/associations will be formed to increase the quality and efficiency of hospital services. Hospital unions will be empowered through the decentralisation of authority. Private sector investments in health will be encouraged and all hospitals will be privatised gradually following pilot studies. Health Accreditation Systems will also be devised to increase the quality of care by setting international standards for health services and personnel.

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Mythbusters

Myth: Generic drugs are lower quality and less safe than brand name drugs

To Shakespeare's Juliet, a rose by any other name would smell as sweet. However, when it comes to prescription drugs and Canadians, there is a lot in a name after all. Although generic drugs are widely used in hospitals, and provincial drug programmes try to persuade people to take generic versions of prescription drugs, research evidence suggests some feel uneasy about making the switch.^{1,2} In addition to concerns generics are less safe and less effective than brand-name drugs,^{1,2} some patients worry generics cause too many side-effects and are not favoured by their physicians.¹

The problem is worsened by the fact few health care professionals initiate conver-

sations with their patients about generic drugs.¹ In addition, factors such as patient pressure, a lack of information about generic drugs, and loyalties to drug manufacturers may make physicians more apt to prescribe brand-name drugs,^{6,7} which may further instil doubts about generic medicines.

It all can leave Canadians wondering why provincial drug plans have adopted 'generics-first' policies, where less costly but equivalent generic drugs are substituted for brand-name medicines.⁸ In addition, they may worry that quality and safety are being compromised for the sake of the bottom line.

Different look, same quality

Generic drugs have the same medicinal ingredients as their brand-name counterparts.⁹ The principal difference between them is that only after the patents on brand-name products have expired may generic companies produce their products.^{10,11} Generic drugs are usually less expensive¹²⁻¹⁴ – costing on average 45% less than the brand-names¹⁰ – but may have a different shape or colour than brand-name counterparts.¹⁰ These drugs are often made by large, generic manufacturers. Interestingly, a 2004 estimate finds 27% of generic medicines – so called 'pseudogenerics' – on the Canadian market are made by brand-name companies.¹⁵

Whoever makes them, all prescription drugs in Canada undergo a review by Health Canada, where drug ingredients are checked and manufacturing processes and facilities are verified against the same federal guidelines.⁸⁻¹⁰

Ingredients are the most important element in the review process. Medicinal or active ingredients must meet the same Health Canada standards whether the drug is a generic or brand-name.^{9,10} Manufacturers are required to test each drug batch, both during and after

Comparison of prices of four brand-name and generic drugs approved for sale in Canada^{a,b}

Use (form)	Brand-name (strength)	Brand-name price (\$) per single dose ^c	Generic	Generic price (\$) per single dose ^c
Antibiotic (tablet)	Zithromax (250 mg)	4.63	azithromycin	3.11
Cholesterol-lowering (tablet)	Zocor (80 mg)	2.24	simvastatin	1.39
Heartburn (tablet)	Zantac (150 mg)	1.08	ranitidine	0.40
Ulcers (tablet)	Losec (20 mg)	2.20	omeprazole	1.25

- Each of the drugs in this table has been approved for sale in Canada.³
- These drugs were selected from the 200 most frequently prescribed drugs in Canada in 2005 and 2006.⁴
- Although prices come from the Quebec formulary as of 18 April 2007,⁵ there is little price variation across provinces. These prices are the wholesale prices and do not include pharmacist mark-ups or dispensing fees. Prices have also been rounded up to the nearest hundredth.

Mythbusters are prepared by Knowledge Transfer and Exchange staff at the Canadian Health Services Research Foundation and published only after review by a researcher expert on the topic.

The full series is available at www.chsrf.ca/mythbusters/index_e.php. This paper was first published in 2007. © CHSRF, 2007.

production, to demonstrate they are equally safe and effective.⁸⁻¹⁰ In cases where the generic's non-medicinal ingredients, which give it its colour and shape, are different from the brand-name's, manufacturers must provide research to show the drug meets the standard.⁹

Generic drug companies ultimately have two options to prove their products are safe and effective. They may run their own clinical drug trials, repeating most of the testing the brand-name manufacturers have carried out.⁹ Or they may show how their drug compares with the original brand-name drug in tests of 'bioequivalence.'⁹ Most generic drug companies opt for the latter option since the original brand-name drug has already been proven safe and effective.⁹ If either test proves successful, Health Canada will give its approval, allowing the generic to be substituted for the brand-name

Smart substitution

Despite evidence some Canadians may be reluctant to embrace generic drugs, chances are most have taken these medications before. Generic drugs accounted for 43% of all prescriptions filled for Canadians in 2005.¹⁶ Generic equivalents are not always available on the market. And some literature indicates there are a minority of cases where changing the drug that is administered may be inappropriate, particularly for drugs that are safe only when a precise dosage is administered.¹⁴

The example commonly cited in the research literature has shown patients with epilepsy may be sensitive to changes in the brand of their anti-seizure medications.^{14,17} However, it also appears there are generics from this class that are safe to substitute.¹⁸ Moreover, there are thousands of generics on the market, all of which appear to be well-tolerated by those who can use them (knowingly or otherwise, as the case may be). While there are always individual differences to how people react to any drug, prescribing generic drugs, where appropriate, can be effective and save money.

Conclusion

Generic drugs must pass the same level of scrutiny from Health Canada as their brand-name counterparts. In the end, consumers and possibly some prescribers may need to rethink some of their assumptions about whether reserving a place for brand-name drugs on their medicine shelf is always best.

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Gout and drinking

People with gout, and their carers, tend to be obsessive when it comes to food, and especially drinking; alcohol and coffee are often banned completely. All of which makes for a bland existence, which is why a frequently asked question is what gout sufferers can drink without exacerbating their condition.

A large US survey has reported on coffee, tea, and various forms of alcohol.^{1,2} The results will warm the cockles of some hearts.

Studies

A representative sample of the US population was selected and studied between 1988 and 1994. Subjects were interviewed at home, and attended an examination, with blood and urine sample collection. During the interviews, a food frequency questionnaire was used which ascertained the frequency of consumption of coffee, tea, and alcoholic beverages, as well as soft drinks that might contain caffeine. Serum uric acid was also measured.

Results

The survey used data from over 14,000 people aged over twenty years of age. Those with gout, or taking allopurinol or uricosuric agents were excluded.

Coffee, tea, and caffeine

Using a quintile of consumption approach, uric acid levels were identical across quintiles of intake of total caffeine and tea. For coffee (including decaffeinated), drinking more than four cups of coffee a day significantly lowered serum uric acid levels, by about 8% at maximum (Figure 1). The reduction of uric acid by coffee remained after adjusting for a whole range of variables and dietary factors.

Alcohol

Using the quintile of consumption approach drinking wine did not affect serum uric acid levels at any level of consumption up to one serving per day or more. The consumption of spirits, and especially beer, did increase serum uric acid levels (Figure 2), even after adjusting for a whole range of factors. Beer and spirits drunk daily increased serum uric acid by about 10%; wine did not. The results were similar in men and women, and at lower and higher levels of body mass index.

Figure 1: Reduction in mean serum uric acid levels according to quintiles of daily intake of coffee

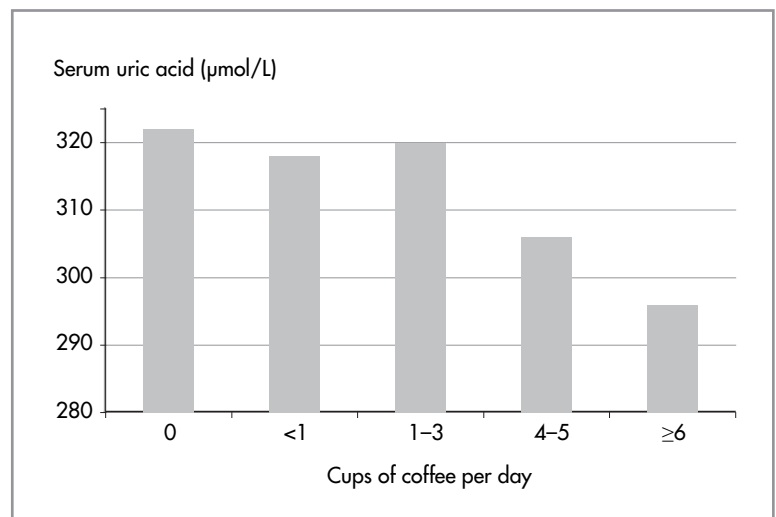
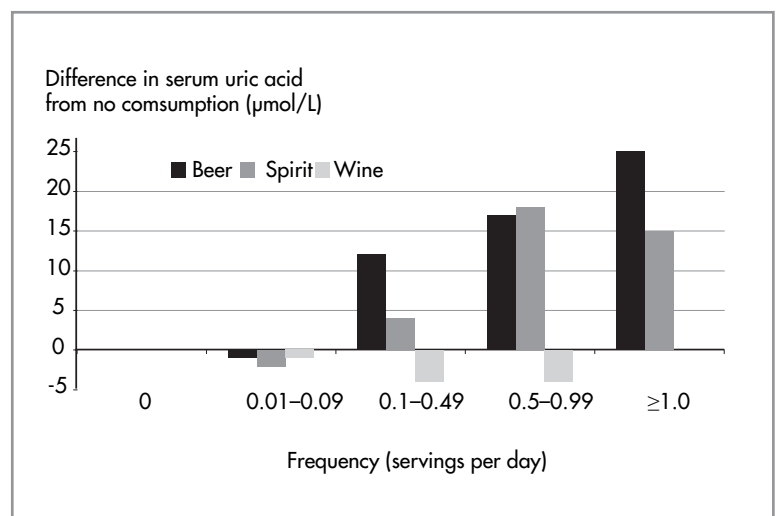


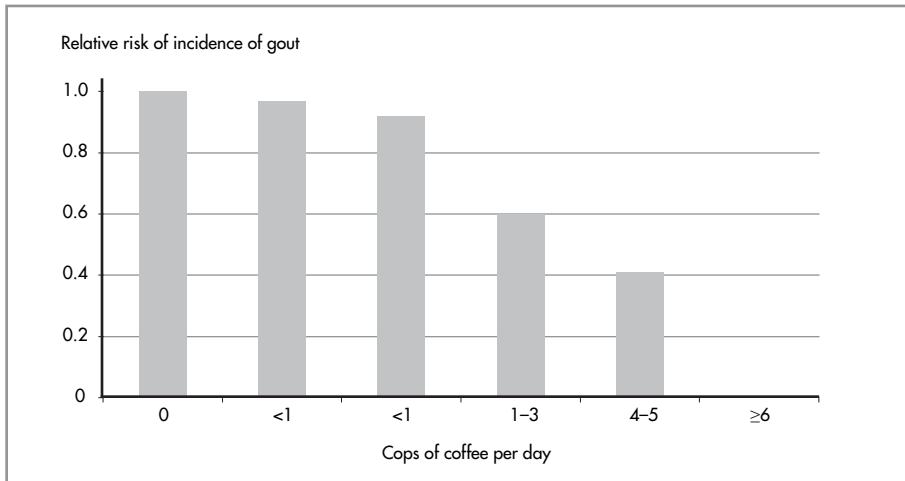
Figure 2: Effect of different daily consumption (quintiles) of different alcoholic beverages on mean serum uric acid levels



Bandolier is an online journal about evidence-based healthcare, written by Oxford scientists. Articles can be accessed at www.jr2.ox.ac.uk/bandolier

This paper was first published in 2007. © Bandolier, 2007.

Figure 3: Relative risk of incident gout in 12-year follow up of 46,000 men, according to quintiles of daily coffee consumption



Comment

This constitutes useful additional knowledge about what gout sufferers might do to avoid increasing their serum uric acid, and perhaps precipitating an attack, or making the pain worse. Drinking beer and spirits are out, but tea and wine have no effect, while coffee actually seems to reduce uric acid levels. We have had some straws in the wind about coffee before, but this adds weight.

More weight comes from a large study of coffee consumption and incident gout in men,³ following 46,000 men with no history of gout at baseline for twelve years. There were 750 cases of incident

gout, and the risk was lower with higher coffee consumption, before and after adjustment for a whole host of different possible confounding factors (Figure 3). So increased coffee drinking is linked with both reduced serum uric acid levels and reduced incidence of clinical gout.

We also have information about what we eat and the risk of incident gout.⁴ This has been examined in detail on the Bandolier Internet site, but the main results are worth reiterating. Increased consumption of meat was associated with increased risk of gout, but only with beef, pork, and lamb. There was less association with seafood, and none with purine

rich vegetables. Increased consumption of dairy food reduced the risk of gout. We find the same now for uric acid⁵ where high meat and to a small extent seafood consumption is associated with higher uric acid levels, but dairy food with lower uric acid levels. Much food for thought for those with gout and for healthy eating.

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Pre-announcement: Observatory Venice Summer School 2009

'Innovation and Health Technology Assessment: Improving Health System Quality'

The European Observatory on Health Systems and Policies and the Region of Veneto announce the next annual Observatory Venice Summer School which will take place on the island of San Servolo, 26–31 July 2009

The target audience is senior to mid-level policy-makers and more junior professionals who are making careers in policy and management at a regional, national or European level. All participants should be working in institutions with decision-making powers, relevant provider or payer associations or public HTA agencies or professional bodies. Applications are welcome from all countries in the European Region.

The Summer School is accredited by the European Accreditation Council for Continuing Medical Education.

Topic: The 2009 school will look at the role of innovation and Health Technology Assessment (HTA) as tools for improving quality and outcomes of health care. The course will have an emphasis on HTA, its implications and the associated demands as regards information, including identifying when innovation or new research is needed. It will bridge the gaps between generalist system planning; specialist HTA expertise; and the impact on practitioners of HTA led developments.

Objectives: The aim is to raise key issues; share participants' insights (whether they are practitioners or analysts), and build networks. Specifically, the Summer School aims to develop a greater understanding of (1) the challenges of innovation in health technologies and health care delivery – and how to ensure that services are safe, effective, appropriate and cost-effective, (2) how evidence and context interact and (3) how evidence impacts on clinical practice and on policy processes.

Outline: This 5-day course consists of lectures, short presentations from participants, discussions and group work. The approach will be participative, but there will be a core of formal teaching (in English). It will address systems for developing and assessing health care products (drugs, diagnostics and devices) as well as clinical and policy interventions, such as regulatory approval, reimbursement systems and national guidance. It will also look at how evidence is used and how HTA and innovation contribute to quality improvement programmes and strategies.

Faculty: The course will be led by Professor Reinhard Busse, the Observatory and Berlin University of Technology, and John-Arne Røttingen of the Norwegian Knowledge Centre for Health Services and the Observatory, with international experts and practitioners serving as lecturers and facilitators.

Organization: Applications with CVs will be invited in a formal announcement shortly. A selection process will follow and a limited number of bursaries will be available.

For more details, visit www.observatorysummerschool.org or email summerschool2009@obs.euro.who.int

Eurohealth aims to provide information on new publications that may be of interest to readers. Contact Sherry Merkur at s.m.merkur@lse.ac.uk if you wish to submit a publication for potential inclusion in a future issue.

Good practices in health financing: lessons from reforms in low- and middle-income countries

Edited by: P Gottret, GJ Schieber and HR Waters



Washington: The International Bank for Reconstruction and Development / The World Bank, 2008

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504 pages

Freely available online at:
<http://siteresources.worldbank.org/INT/HSD/Resources/376278-1202320704235/GoodPracticesHealthFinancing.pdf>

This book systematically assesses health financing reforms in nine low and middle-income countries that have demonstrated “good performance” in expanding their populations’ health insurance coverage – to both improve health status and protect against catastrophic medical expenses. Good performance also includes average or better-than-average population health outcomes relative to resources devoted to health, national income and educational levels.

Among the countries that are in the process of achieving high levels of population coverage and financial protection, nine were selected as examples of good performance by an expert steering committee, these include: Chile, Colombia, Costa Rica, Estonia, the Kyrgyz Republic, Sri Lanka, Thailand, Tunisia and Vietnam. Each country case is analysed using a standardised taxonomy that captures the key health and non health sector-specific factors affecting the

performance of its health financing.

The study seeks to identify common enabling factors of their good performance. While the findings for each country are important, the volume sends a clear message to the global community that more attention is needed to define “good practice” and then to evaluate and disseminate the global evidence base.

Contents: Foreword; Acknowledgments; Executive summary; Acronyms and abbreviations;

Part 1 – Assessing good practice in health financing reform:

1. Introduction;
2. Health financing functions;
3. Criteria for defining ‘good practice’ and choosing country cases;
4. Summaries of country cases;
5. Enabling factors for expanding coverage;

Part 2 – Nine case studies of good practice in health financing reform; Appendix A; Index.

Health technology assessment and health policy-making in Europe. Current status, challenges and potential

Edited by: MV Garrido, FB Kristensen, CP Nielsen and R Busse



Copenhagen: World Health Organization on behalf of the European Observatory on Health Systems and Policies, 2008

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181 pages

Freely available online at:
<http://www.euro.who.int/Document/E91922.pdf>

Health technology assessment (HTA) aims to inform health policy and decision-making processes concerning health technologies on organisational, societal and ethical issues. HTA has a strong foundation in research on the health effects and broader implications of the use of technology in health care. Its potential for contributing to safer and more effective health care is widely acknowledged in Europe and interest in this field has been growing steadily.

Since the establishment of the first national HTA agency in Sweden in the 1980s, the number of institutions involved in the assessment of health technologies has multiplied in Europe. Most European Union Member States have established a formal HTA programme or are considering the feasibility of establishing HTA intelligence to inform health policy-making. Since its inception, the HTA community has acknowledged the need for international collaboration and networking.

As a result of these developments, this book has been produced as a collabo-

ration between the EUnetHTA Project and the European Observatory on Health Systems and Policies with the aim of reviewing the relationship between HTA and policy-making from different perspectives, with a special focus on Europe. The aim is to transmit the value of HTA more broadly to decision makers and health care managers in order to increase their awareness of HTA activities and evidence-based decision making.

Contents:

- Introduction;
1. Transnational collaboration on HTA – a political priority in Europe;
2. Policy processes and HTA;
3. What is HTA?
4. Health systems, health policy and HTA;
5. HTA in Europe – an overview of the producers;
6. What are the effects of HTA reports on the health system? Evidence from the research literature;
7. Needs and demands of policy-makers;
8. Future challenges for HTA in Europe.

Czech EU Presidency 2009

News and information from the Czech presidency of the European Union

<http://www.vlada.cz/en/eu/predsednictvi/predsednictvi/default.html>

eHealth ERA

<http://www.ehealth-era.org>

The objective of the eHealth ERA project is to contribute to the coordination of Member States' eHealth strategy formulation and implementation, as well as eHealth-related research and technological development, by establishing an European Research Area (ERA) in the subject. The English language web site provides a database containing documents on national eHealth priorities, strategies, roadmaps, programmes, as well as the contact details of experts for EU and other countries. The site also contains news on eHealth related events, downloadable publications, a newsletter and links to other relevant organisations.

European Union of Medical Specialists (UEMS)

<http://www.uems.net>

The UEMS represents national associations of medical specialists in thirty-five EU and associated countries. The English and French language web site provides links to the national associations, as well as details of meetings, UEMS charters and declarations, annual reports, position papers and a newsletter. Documentation of working groups covering the following topics is made available: eHealth, postgraduate training, quality in patient care and specialist practice in current health systems. In addition, the site hosts the web pages of the European Accreditation Council for Continuing Medical Education and makes available reports from all member countries on the structure and development of Continuing Medical Education and Professional Development (CME-CPD).

Gapminder

<http://www.gapminder.org>

Gapminder is a non-profit venture aiming to promote sustainable global development through increased use and understanding of statistics at local, national and global levels. The English-language web site makes time series data freely available in the form of ready-made videos, Flash presentations and PDF charts showing major global development trends with animated statistics and colourful graphics. In addition to various economic, demographic, social and environmental indicators, various basic mortality and morbidity indicators are available. Data is available both at the country level and additionally at the sub-national level for China, India and the USA.

NHS Confederation

<http://www.nhsconfed.org>

The NHS Confederation is an independent membership body of NHS organisations across the UK. The web site hosts the *Health Services Research (HSR) Network*, a network of over one hundred organisations, including sixty groups of health services researchers in universities, other institutes and forty NHS bodies, and also the *SDO Network*, a network of NHS Trusts. The web site provides emailed daily press summaries and a weekly *Interchange Alert*. It also contains briefing and consultation papers, reports and detailed discussion documents. Policy networks give electronic updates on specific policy issues. There are also details of the Confederation's annual conference, exhibition and one-day conferences, as well as meetings on specific policy areas.

European Society for Quality in Healthcare (ESQH)

<http://www.esqh.net>

The Limerick-based ESQH is a not-for-profit organisation dedicated to the improvement of quality in European health care. It consists of nineteen member national societies. The English language web site provides news, contact information for the national members, details and documentation from various workgroups, information about European funded projects and conferences, including downloadable presentations and links to related web sites.

PRIORITIES OF THE CZECH RESIDENCY

The overarching priorities of the Czech Presidency are the three 'E's': Economy, Energy and Europe in the world. Unsurprisingly, much attention is focused on ways of addressing the global credit crunch and strengthening energy security through further diversification of energy supplies from external sources.

Priorities for health

Financial Sustainability

One key area to be addressed within the health programme concerns the implications of the global economic credit crunch. Already questions are beginning to be asked about the financial sustainability of different health care systems. The Presidency will focus primarily on the definition of financial sustainability and its objectives, and on the analysis of the resources available for health care funding. In terms of long-term care funding, attention will be drawn to the pressure it faces as a result of the growing demand for services, in relation both to negative demographic trends and the lack of providers of this type of care. A May 2009 high-level conference is to provide a forum for Member States to share experience and exchange information and best practice concerning health care systems and their financial sustainability.

Patient safety

The main objective of the initiative addressing patient safety and health care quality is to provide support to Member States in their efforts to ensure safety and quality standards, namely the continuous quality improvement (CQI) of health care and patient safety within national and regional systems. The Presidency will also participate in the adoption of appropriate measures for infection control and the definition of relevant standards and preventive measures. The prevention and control of antimicrobial resist-

ance and health care-associated infections, with an emphasis on European hospitals, will be a priority. An April 2009 ministerial conference is expected to provide recommendations for specific measures concerning antibiotic programmes in European hospitals and suitable models for the support and financing of these programmes by national governments and health care payers, especially health insurance companies.

Pharmaceuticals and other priorities

The pharmaceutical package contains proposals on three key issues: to improve the functioning of the pharmacovigilance system at European level, to strengthen the legal distribution chain for pharmaceuticals against illegal or counterfeit products and to provide the general public with information on prescription pharmaceuticals (see article below).

Other elements in the health programme include further work to set out an overall framework for the provision of cross-border health care. The Presidency will also seek to address the growing mobility of health care workers. In respect of the quality and safety of organ donation and transplantation, a new legislative initiative will include principles providing a general framework for quality and safety in relation to the medical use of human organs; the creation of a common set of quality and safety standards for organ transport and storage; and reporting serious adverse events.

The Presidency is also looking into the issue of improving cooperation between Member States, increasing the quality of health care provision with the help of telemedicine, and strengthening the interoperability of information systems in the healthcare sector. In February 2009, the topic of e-Health will be discussed at a ministerial conference.

Health in all policies

Health issues are also covered through a number of actions and initiatives to be found in different policy areas.

Road safety

One health-related theme within transport policy is road safety. The high number of people killed on European roads requires an enhancement of Europe-wide efforts to improve road safety. One objective is to begin discussion on the future orientation of EU policies concerning road safety. The outcome should be the adoption of a new European Road Safety Action Programme for 2011–2020 in the second half of 2009 or in the first half of 2010.

e-Accessibility

Within telecommunications the Presidency will focus on overcoming barriers via information and communication technologies. This includes work on inclusion into the information society (e-Inclusion), including the issue of the accessibility of information and communication technologies to older people and those with disabilities (e-Accessibility).

Health and the environment

Health is a major aspect of the environmental programme. It focuses on a number of specific issues including: progress in the proposal for a directive on industrial emissions; finalising the discussions on the review of the proposal for the regulation on ozone-depleting substances; initiating discussions on a proposed review of the directive on national emission ceilings for certain atmospheric pollutants, if submitted by the Commission; and discussions on proposals for directives reviewing the management of waste electrical and electronic equipment.

The Presidency will also discuss the management of biowaste, in connection with the European Commission's published Green Paper. It will also coordinate a number of international meetings and activities on the protection of

the environment and health, for example, negotiations on long-term international legally-binding measures to reduce risks from releases of mercury to prevent further environmental contamination at a global level during the 25th session of the Governing Council of the United Nations Environment Programme, in February 2009 in Nairobi, and represent the EU during these events.

Active inclusion

Within the field of employment and social policy, the programme will focus on services as a tool for preventing social exclusion and for active inclusion of vulnerable groups. The Presidency will organise a conference to discuss social inclusion issues and will propose the adoption of the Council conclusions. Attention will also be paid to the improvement of quality, the availability and financing of long-term care, protection of the dignity and rights of people dependent on care, and support for an active, healthy ageing and ageing well.

More information on Presidency priorities at <http://www.eu2009.cz/en/czech-presidency/programme-and-priorities/programme-and-priorities-479>

EUROPEAN MONITOR

Europe needs to intensify and double cancer screening

Cancer is the second most common cause of death in the EU. Breast, cervical and colorectal cancer accounts for 32% of cancer deaths in women and 11% in men. With an ageing population, the figures are due to increase unless preventive measures are taken. The EU shares a common commitment to ensuring proper screening for breast, cervical and colorectal cancer, as set out in Council Recommendation of 2 December 2003 on cancer screening (2003/878/EC). In the first implementation report, the Commission highlights that, although much progress has been made in the field of cancer screening, Member States have not fully put screening in place.

Findings

The report notes that while the current annual volume of screening examinations in the EU is considerable, this is less than half the minimum number that would be expected if the tests specified in the Council Recommendation on cancer screening were available to all EU citizens

of appropriate age (approximately 125 million examinations per year). Less than half of these examinations (41%) are performed in population-based programmes which provide the organisational framework for implementing comprehensive quality assurance as required by the Council Recommendation. Only twenty-two Member States are running or establishing population-based screening programmes. For cervical and colorectal cancer screening programmes this falls to fifteen and twelve Member States respectively.

The way ahead

By providing a clear description of the situation and the gaps, the report helps to renew the commitment to put in place breast, cervical and colorectal cancer screening as a crucial and cost-effective measure to reduce the burden of cancer in the EU.

The report indicates that Member States need to continue to improve or implement population-based cancer screening programmes. Additional efforts should be made to improve and maintain screening measures to assure the quality, effectiveness and cost-effectiveness on a Member State as well as EU level.

At an EU level, the Commission intends to form a European partnership for action against cancer in 2009 by bringing together relevant stakeholders across the EU. Key areas for future cancer activities will include: health information, collection and analysis of comparable data; primary prevention; identification and promotion of good practice in cancer-related healthcare; priorities for cancer research.

The European Commissioner for Health, Androulla Vassiliou, said that "in these times of financial uncertainty, we need to recognise, more than ever, the importance of planning for a healthy future. Investing in cancer screening programmes will pay long term dividends, as prevention is the most efficient and cost-effective way to minimise the European burden of cancer."

The Report on the Implementation of the Council Recommendation of 2 December 2003 on cancer screening is available at http://ec.europa.eu/health/ph_determinants/genetics/keydo_genetics_en.htm

The Council Recommendation of 2 December 2003 on cancer screening is available at <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2003:327:0034:0038:EN:PDF>

Commission takes steps to promote patient safety in Europe

Each year in the EU between 8% and 12% of patients admitted to hospitals suffer harm from the health care they receive, including from health care associated infections (HCAI). Much of that harm is preventable. On 15 December, the Commission adopted a Communication and proposal for a Council Recommendation with specific actions that Member States can take, either individually, collectively or with the Commission, to improve the safety of patients.

The Communication follows a recent public consultation on patient safety and an earlier consultation on the specific threat to safety posed by HCAI. Working groups representing Member States and key stakeholder groups, including health professionals and patients, contributed to discussions on both the issue of general patient safety aspects and on health care associated infections in particular.

Speaking of the Communication, Commissioner for Health, Androulla Vassiliou, stated that "patient safety is the cornerstone of good quality health care. I would like to see a Europe for patients where safety is paramount and citizens are confident and knowledgeable about the care they receive."

According to the European Centre for Disease Control (ECDC), each year 4.1 million patients in the European Union have a hospital acquired infection, equivalent to one in twenty hospitalised patients. The additional costs to European health systems have been estimated conservatively to be €5.48 billion per year.

Well-known examples of such infections include those caused by the bacterium MRSA (meticillin-resistant *Staphylococcus aureus*). However, recent studies have shown that HCAI can be reduced by up to a third when certain infection prevention and control measures and structures are put in place.

The most common types of adverse events in health care are: HCAI; incorrect or delayed diagnoses; surgical errors; and medication related errors. Most efforts to improve patient safety at Member State and EU levels have so far focussed on specific causes, for example, minimising the risk from medicinal products, medical devices or antimicrobial resistance. However, most adverse events are caused by a combination of factors which together result in harm to patients.

The Commission Communication thus recommends a comprehensive approach to improving patient safety. The primary focus is on addressing systemic and organisational failures responsible for most harm to patients. In respect of infections, key recommendations for Member States include: putting in place specific measures to prevent and control infections; ensuring that infection prevention and control is enhanced in hospitals; and having effective systems in place to detect and report infections. Other patient safety recommendations include: establishing or strengthening reporting and learning systems; embedding patient safety in the education and training of health care workers; involving patients in the development of safety measures; and providing patients with relevant information on health risks and safety issues. Member States are also encouraged to share best practice and expertise in this field. The Commission will work with Member States to develop common definitions and indicators for patient safety.

More information at http://ec.europa.eu/health/ph_systems/patient_safety_en.htm

Antitrust: preliminary report on pharmaceutical sector inquiry

On 28 November the European Commission published its preliminary report on the competition inquiry into the pharmaceutical sector. A sector inquiry is an information gathering exercise that provides the Commission with in-depth knowledge about markets, with a view to better identifying obstacles to competition. Essentially, the Commission opens a sector inquiry when it has concerns that competition may not be working as it should, but the reason for this is not clear. This inquiry began in January 2008 to examine why fewer new medicines were brought to market and why generic entry seemed to be delayed in some cases.

Publication of the controversial report followed two separate raids on the offices of major pharmaceutical firms last year. The manner of the investigation was strongly criticised by industry representatives, but the Commission justified its actions by saying it believed some companies may be engaged in “restrictive business practices and/or the abuse of a dominant market position”.

The preliminary report concludes that competition in this industry does not work as well as it should. It states that originator companies (that develop and

sell new medicines) used a variety of methods to maintain high income streams by delaying or blocking market entry of generic companies and other originator companies.

Practices vis-à-vis generic companies include multiple patent applications (in one case 1,300) for the same medicine (so-called patent clusters), as well as the initiation of disputes and litigation, with nearly 700 cases of reported patent litigation with generic companies, on average lasting almost three years. Originator companies also concluded more than 200 settlement agreements with generic companies in the EU, in which they agreed on the terms for ending an ongoing litigation or dispute. More than 10% of the settlements were so-called ‘reverse payment settlements’ which limited the entry to the market of the generic medicines and provided for payments from the originator to the generic companies. These payments amounted in total to more than €200 million. Originator companies also intervened in national procedures for the approval of generic medicines in a significant number of cases, which on average led to four months of delay for the generic medicine.

Where successful, these practices result in significant additional costs for public health budgets – and ultimately taxpayers and patients – and reduce incentives to innovate. Based on a sample of medicines that faced generic entry in the period 2000–2007, average price levels for medicines decrease by almost 20% after the first year following generic entry. In rare cases, the decrease in price levels can be as high as 90%. For the sample under analysis, total savings gained by generic entry amounted to at least €14 billion over the period. Without these savings, total expenditure for the medicines analysed would have been over 25% higher.

The inquiry confirmed that generic entry often occurs later than expected. On average it took about seven months for generic products to enter the market on a weighted average basis and even the top-selling medicines faced an average delay of four months. Given the strong impact of generic entry, this amounted to lost savings of about €3 billion to health systems during 2000–2007 for the chosen sample of medicines facing patent expiry in 17 Member States. In relative terms it could have reduced the bill for these medicines by over 5%. The preliminary findings suggest that the practices under

investigation contributed to these shortcomings.

Stakeholders also made a significant number of comments on the regulatory framework. In particular, both generic and originator companies called for a single Community Patent and the creation of a unified and specialised patent judiciary in Europe. These calls are also supported by the preliminary findings of the inquiry. It discovered 11% of contradictory final judgments in litigation cases and total direct costs associated with the patent litigation of €420 million. Such contradictions and the costs related to the litigation could be avoided, or as a strict minimum reduced, with a Community Patent and an unified specialised patent judiciary.

Competition Commissioner Neelie Kroes said that “competition in the pharmaceuticals market is vital for people to get affordable and innovative medicines, and to make sure that taxpayers get the best value for money out of their health care system. These preliminary results show that market entry of generic companies and the development of new and more affordable medicines is sometimes blocked or delayed, at significant cost to health care systems, consumers and taxpayers. We now have a solid view of what is happening and why: the next step is to discuss our findings with the stakeholders and to draw the necessary conclusions. It is still early days, but the Commission will not hesitate to open antitrust cases against companies where there are indications that the antitrust rules may have been breached.”

Following the publication of the preliminary report, a public consultation ran until 31 January 2009. More than forty submissions to the consultation process were received. These will be posted online within weeks, the EU executive has now confirmed. A final report is due later in the year.

The preliminary report and more information on the inquiry are available at <http://ec.europa.eu/comm/competition/sectors/pharmaceuticals/inquiry/index.htm>

New pharmaceutical legislation unveiled

On 10 December the European Commission unveiled new pharmaceutical legislation designed to improve medicinal information available to patients and combat the growing prolifer-

ation of counterfeit medicines in the EU. Commission Vice-President Günter Verheugen said the priority of the 'pharma package' was patients' health and safety, although he stressed that having a "healthy European pharmaceutical sector" was very important too. Verheugen expressed his hope that the package would help Europe to achieve its goal of being "the chemist of the world" and the global "standard bearer for high quality bio-tech work".

A key aspect of the package proposes stricter rules on the availability of information about prescription-only medicines. The Commission wants to give patients access to centralised EU information on their side effects. Moreover, to ensure clarity of information, the EU executive calls for advertising of prescription medicines to be scrapped. It also wants to introduce stricter rules regarding the content of pharmaceutical adverts, including those on the internet, in the form of an EU code of conduct.

A further important element of the package concerns the fight against counterfeit medicines, imports of which have risen steadily for the past three years. Some 2.5 million packages of counterfeit medicine were seized at EU borders in 2007. To tackle the growing problem, Commissioner Verheugen said the package outlined "various steps to make sure the supply chain is secure".

The Commission is proposing to introduce three safety features to ensure the 'total traceability' of all medicines bought in pharmacies or online. These are a (still to be finalised) standardised barcode, an authenticity feature guaranteeing that a medicine's contents are what they should be and a standard seal to provide protection from tampering.

The proposed legislation has met with a mixed response. Monique Goyens, Director General of The European Consumers' Organisation (BEUC), dismissed the guidelines as being just "a disguised way of giving pharmaceutical companies greater flexibility to provide the information they want on prescription medicines directly to the public, namely direct-to-consumer communication strategies – the goal of which in our view is to boost sales." The European Generics Medicine Association (EGA) also raised concerns over the "possible misuse of information as a marketing tool," adding that it is "crucial that the proposal ensures

better – rather than simply more - information to patients in order to avoid any form of direct marketing and exerting undue commercial influence over consumers."

In contrast, Arthur J Higgins, Chief Executive Officer of Bayer HealthCare and president of the European Federation of Pharmaceutical Industries and Associations (EFPIA), welcomed the publication of the pharma package saying that we "recognise the benefit to EU citizens and patients of the new provisions for pharmacovigilance and improved access to health and medicines information." However industry stakeholders claimed that the EU executive failed to adequately address the problem of counterfeit drugs sold on the internet. The European Generic Medicines Association (EGA) also said "solutions should focus on where the problems are. The EGA therefore is concerned that the main source of counterfeiting, the internet, is not addressed by the package".

The Commission's proposals will now be submitted to the European Parliament and European Council, where they will be discussed and voted upon under the co-decision procedure. The measures could become law within eighteen months.

More information on the proposed legislation available at http://ec.europa.eu/enterprise/pharmaceuticals/pharmacos/pharmapack_en.htm

European Court of Auditors criticises EC development health financing

The European Court of Auditors has published a report looking at the European Commission's (EC) financing for health in sub-Saharan Africa. The report was a response to a 2007 mid-term review by the United Nations of progress on all the Millennium Development Goals (MDGs). This report, while acknowledging the failure to meet MDG goals across the world, observed that least progress had been made in Sub-Saharan Africa.

The objective of the audit was to assess how effective EC assistance has been in contributing to improving health services in sub-Saharan Africa in the context of the EC's commitments to poverty reduction and the Millennium Development Goals (MDGs). The audit examined whether the financial and human resources allocated to the health sector reflected the EC's

policy commitments and whether the Commission had accelerated the implementation of this aid. The audit also assessed how effectively the Commission had used various instruments to assist the health sector, notably budget support, projects and the Global Fund to fight AIDS, tuberculosis and malaria.

Overall, the report noted that EC funding to the health sector has not increased since 2000 as a proportion of its total development assistance, despite the Commission's MDG commitments and the health crisis in sub-Saharan Africa. While the Commission contributed significant funding to help launch the Global Fund, it has not given the same attention to strengthening health systems, although this was intended to be its priority. The Commission was also criticised for having insufficient health expertise to ensure the most effective use of health funding.

Although the Commission was found to have accelerated the health assistance it manages itself, its rate of disbursement has been slower than for the European Development Funds (EDF). The report argues that there is scope for improving the predictability of the flow of funding from all instruments to enable countries to better budget the resources available for their health sectors.

It also noted that the Commission has made little use of Sector Budget Support in the health sector, although this instrument could make an important contribution to improving health services. It has used General Budget Support much more widely but its links to the health sector are less direct and the Commission has not used it very effectively. Overall, projects have proved reasonably effective although sustainability is often problematic. The Commission played a key role in setting up the Global Fund, which has already produced significant outputs, but greater involvement by the Commission in Global Fund activities in the beneficiary countries could have made it more effective.

The Commission also did not pay sufficient attention to ensuring the different instruments are used together coherently. When choosing which instruments to use, it could also take more account of the situation in individual countries, in particular whether they had a well defined health sector policy.

The report's main recommendations are

that the Commission should: consider increasing its aid to the health sector during the tenth EDF midterm review to support its commitment to the health MDGs; review how its assistance to the health sector is distributed to ensure it is primarily directed to its policy priority of health systems support; ensure each Delegation has adequate health expertise either in the Delegation or through drawing on the resources of other partners; make more use of Sector Budget Support in the health sector and focus its General Budget Support more on improving health services; continue to use projects, especially for support to policy development and capacity building, pilot interventions and assistance to poorer regions; - work more closely with the Global Fund in beneficiary countries; establish clearer guidance on when each instrument should be utilised and how they can best be used in combination; and make greater efforts to contribute to the development of well defined health sector policies in beneficiary countries.

*The report can be accessed at
<http://eca.europa.eu/portal/pls/portal/docs/1/2020216.PDF>*

Injuries killing more than 2,000 children everyday

On 10 December a joint report by the WHO and UNICEF was launched on child injury prevention in Geneva. Worldwide more than 2,000 children die every day as a result of unintentional or accidental injuries. Every year tens of millions more are taken to hospitals with injuries that often leave them with lifelong disabilities.

The World Report on Child Injury Prevention provides the first comprehensive global assessment of unintentional childhood injuries and prescribes measures to prevent them. It concludes that if proven prevention measures were adopted everywhere at least one thousand children's lives could be saved every day.

"Child injuries are an important public health and development issue. In addition to the 830,000 deaths every year, millions of children suffer non-fatal injuries that often require long-term hospitalisation and rehabilitation," said WHO Director-General Dr Margaret Chan. "The costs of such treatment can throw an entire family into poverty. Children in poorer families and communities are at increased risk of injury because they are less likely to benefit from prevention programmes and

high quality health services."

"This report is the result of a collaboration of more than 180 experts from all regions of the world," said UNICEF Executive Director Ann M. Veneman. "It shows that unintentional injuries are the leading cause of childhood death after the age of nine years and that 95% of these child injuries occur in developing countries. More must be done to prevent such harm to children."

Africa has the highest rate overall for unintentional injury deaths. The report finds the rate is ten times higher than in high-income countries in Europe and the Western Pacific such as Australia, the Netherlands, New Zealand, Sweden and the United Kingdom, which have the lowest rates of child injury.

However, the report finds that although many high-income countries have been able to reduce their child injury deaths by up to 50% over the past 30 years, the issue remains a problem for them, with unintentional injuries accounting for 40% of all child deaths in such countries.

Road traffic related injuries kill 260,000 children a year and injure about ten million. They are the leading cause of death among 10–19 year olds and a leading cause of child disability. Drowning kills more than 175,000 children a year; moreover the profound long term consequences (including permanent brain damage) of non-fatal drowning mean that it has the highest average lifetime health and economic impact of any injury type. Other major causes of injuries include fire-related burns which kill nearly 96,000 children a year, 47,000 deaths due to falls and another 45,000 children die each year from unintended poisoning.

"Improvements can be made in all countries," said Dr Etienne Krug, Director of WHO's Department of Violence and Injury Prevention and Disability. "When a child is left disfigured by a burn, paralysed by a fall, brain damaged by a near drowning or emotionally traumatized by any such serious incident, the effects can reverberate through the child's life. Each such tragedy is unnecessary. We have enough evidence about what works. A known set of prevention programmes should be implemented in all countries."

The report outlines the impact that proven prevention measures can have. These measures include: laws on child-

appropriate seatbelts and helmets; hot tap water temperature regulations; child-resistant closures on medicine bottles, lighters and household product containers; separate traffic lanes for motorcycles or bicycles; draining unnecessary water from baths and buckets; redesigning nursery furniture, toys and playground equipment; strengthening emergency medical care and rehabilitation services.

It also identifies approaches that either should be avoided or are not backed by sufficient evidence to recommend them. For example, it concludes that blister packaging for tablets may not be child resistant; that airbags in the front seat of a car could be harmful to children under thirteen years; that butter, sugar, oil and other traditional remedies should not be used on burns; and that public education campaigns on their own don't reduce rates of drowning.

*The report is available at
http://www.who.int/entity/violence_injury_prevention/child/injury/world_report/en/index.html*

EUROPEAN COURT OF HUMAN RIGHTS NEWS

ECHR rules Portugal violated right to provide abortion services on ship

On 4 February in Strasbourg the European Court of Human Rights passed judgment in the case of *Women on Waves and Others v. Portugal* (application no. 31276/05), concerning the Portuguese authorities' decision in 2004 to prohibit the ship *Borndiep*, which had been chartered with a view to staging activities promoting the decriminalisation of abortion, from entering Portuguese territorial waters. At that time, abortion was legal in Portugal only in a few very restricted circumstances, including when the woman's life was in danger. The country subsequently eased restrictions on abortion in 2007, allowing the procedure within the first ten weeks of pregnancy.

The Court held unanimously that there had been a violation of Article 10 (freedom of expression) of the European Convention on Human Rights. Under Article 41 (just satisfaction) of the Convention, the Court awarded each applicant €2,000 in respect of non-pecuniary damage and €3,309.40 for costs and expenses.

Women on Waves had chartered the ship *Borndiep* and sailed towards Portugal after being invited by two Portuguese non-governmental organisations, Clube Safo and Não te Prives, to campaign in favour of the decriminalisation of abortion. Meetings on the prevention of sexually transmitted diseases, family planning and the decriminalisation of abortion were scheduled to take place on board from 30 August to 12 September 2004.

On 27 August 2004 the ship was banned from entering Portuguese territorial waters by a ministerial order, on the basis of maritime law and Portuguese health laws, and its entry was blocked by a Portuguese warship. On 6 September 2004 the Administrative Court rejected a request by the applicant associations for an order allowing the ship's immediate entry.

The court took the view that the non-governmental associations appeared to be intending to give Portuguese women access to abortion procedures and medicines that were illegal in Portugal. The applicant associations appealed against that decision but without success. They subsequently applied to the Portuguese Supreme Administrative Court, which found that the matter in dispute was not of sufficient legal or social significance to justify its intervention.

While the Court acknowledged the legitimate aims pursued by the Portuguese authorities, namely the prevention of disorder and the protection of health, it reiterated that pluralism, tolerance and broadmindedness towards ideas that offended, shocked or disturbed were prerequisites for a 'democratic society'. It pointed out that the right to freedom of expression included the choice of the form in which ideas were conveyed, without unreasonable interference by the authorities, particularly in the case of symbolic protest activities. The Court considered that in this case, the restrictions imposed by the authorities had affected the substance of the ideas and information imparted. It noted that the choice of the *Borndiep* for the events planned by the applicant associations had been crucially important to them and in line with the activities which Women on Waves had carried out for some time in other European States.

The Court observed that the applicant associations had not trespassed on private

land or publicly owned property, and noted the lack of sufficiently strong evidence of any intention on their part to deliberately breach Portuguese abortion legislation. It reiterated that freedom to express opinions in the course of a peaceful assembly could not be restricted in any way, so long as the person concerned did not commit any reprehensible acts.

The Court considered that in seeking to prevent disorder and protect health, the Portuguese authorities could have resorted to other means that were less restrictive of the applicant associations' rights, such as seizing the medicines on board. It highlighted the deterrent effect for freedom of expression in general of such a radical act as dispatching a warship.

The Court therefore concluded that there had been a violation of Article 10, as the interference by the authorities had been disproportionate to the aims pursued.

The full judgement is available (in French only) at
<http://cmiskp.echr.coe.int/tkp197/view.asp?action=html&documentId=846488&portal=hbkm&source=externalbydocnumber&table=F69A27FD8FB86142BF01C1166DEA398649%0D%0A>

COUNTRY NEWS

Italy: constitutional and legal fight over right to die move

Italy's government issued an emergency decree on 6 February to prevent Eluana Englaro, who had been in a coma for seventeen years following a car crash, from having her feeding tubes disconnected.

The case has provoked fierce debate in the country. Her father has been battling with the courts to let her die since 1999, insisting that this was her wish. In November, Italy's highest court ruled that she had expressed a preference for dying over being kept alive artificially, and that doctors could stop feeding her.

She was recently moved to a private geriatric clinic in the city of Udine, where doctors had agreed to disconnect her feeding tubes. But the new decree states that feeding "can in no circumstances be refused". Prime Minister Silvio Berlusconi had said that "urgent government intervention is needed because this morning they began the non-provision of food and water to the person."

The case puts Mr Berlusconi in direct conflict with the courts and President Giorgio Napolitano, who has stated that the decree is unconstitutional and has refused to sign it into law. Two doctors quoted in the leading daily *Corriere della Sera* said that this "process should become irreversible" within "three to five days". Eluana eventually died on 9 February, the date scheduled for an emergency State session, three days after doctors began withdrawing life support.

Opinion polls in Italy show the public is split over this case, although the Vatican has been active in campaigning against attempts to stop feeding Ms Englaro, calling it euthanasia. Euthanasia is illegal in predominantly Roman Catholic Italy, but patients have the right to refuse care. Englaro however has become a symbol for the Church, which retains a heavy influence in Italy, in its campaign against any reform of the law. Cardinal Javier Lozano Barragan, the Vatican's health minister, speaking to the *La Repubblica* daily said that "to stop giving food and liquids to Eluana is equivalent to abominable murder and the Church will not cease to proclaim this loud and clear." His comments came days after Pope Benedict XVI spoke out against euthanasia arguing that those in pain should instead be helped to confront it.

Sweden: survey states one in three doctors in favour euthanasia

One in every three doctors in Sweden is in favour of the legalisation of euthanasia, according to a new survey presented at the *Global Health in a New World* conference in Gothenburg in December. 35% were favourable to the prescription of lethal medicines to patients with an expressed desire to kill themselves. 40% were against and 25% uncertain, according to a report in the newspaper *Svenska Dagbladet*.

"We had thought that opposition was stronger within the medical profession," said Anna Lindblad, based at the Karolinska Institute (KI) that carried out the study and interviewed 1,200 practising physicians. Psychiatrists and older doctors were the groups most positive to allowing euthanasia. Niels Lynöe, a professor of ethics at KI, also expressed surprise at the results of the survey. "It is an unexpectedly high proportion of doctors which would be prepared to help by prescribing medicines to these seriously ill patients," he said.

The Swedish state's medical ethics council (Smer), has recently expressed its support for the idea of doctor-assisted suicide. Smer has called on the government to review the issue but the Minister for Health and Social Affairs, Göran Hägglund, is sceptical.

However, as there are several parties in favour of the legalisation of euthanasia in principle, the issue has the potential to threaten the unity of the coalition government. One recent poll also found that 47% of the general public are also in favour of allowing active euthanasia, according to the magazine Fokus.

England: launch of historic NHS constitution

On 26 January an historic signing ceremony to mark the launch of the NHS Constitution for England took place at the Prime Minister's residence, 10 Downing Street. The Constitution, the first of its kind in the world, was signed by Prime Minister Gordon Brown, Secretary of State for Health Alan Johnson and NHS Chief Executive David Nicholson.

The Constitution will give power to patients and the public by bringing their existing rights together in one place so they know what they are legally entitled to - and how they can exercise their rights as well as understanding their responsibilities. It also contains a range of pledges to patients, public and staff, which the NHS is committed to achieving. For NHS staff, the Constitution will mean an NHS-wide commitment to equipping them with the tools, training and support they need to deliver high quality care for patients.

Speaking at the launch Minister Johnson said "this is a momentous point in the history of the NHS. The launch of the NHS Constitution shows how its founding principles still endure today and have resonance for staff, patients and public alike. It will ensure that we protect the NHS for generations to come."

A review last summer of the NHS by Health Minister Lord Darzi, himself a distinguished medic, concluded that there was a case for an NHS Constitution to enshrine the principles and values of the NHS in England. It is designed to safeguard the future of the NHS and renew its core values, making sure it continues to be relevant to the needs of patients, the public and staff in the 21st century.

The Constitution is the result of extensive consultation with staff and patients, which was led by strategic health authorities and overseen by independent experts on the Constitutional Advisory Forum (CAF). In response to the consultation and report published by the CAF, the final Constitution includes:

- A right to make choices about care and information to help individuals exercise that choice

- A new legal right to receive the vaccinations that the Joint Committee on Vaccination and Immunisation recommends that should be received under an NHS-provided national immunisation programme

- A right making explicit an individual's entitlement to drugs and treatments that have been recommended by the National Institute for Health and Clinical Excellence (NICE) for use in the NHS, if they have been deemed clinically appropriate by that individual's doctor.

- A right to expect local decisions on funding of other drugs and treatments to be made rationally following a proper consideration of the evidence

- Clear and comprehensive rights to complaint and redress.

More information can be found at <http://www.dh.gov.uk/en/Healthcare/NHSConstitution/index.htm>

Bill on Autism to be submitted to UK Parliament

MP for Chesham and Amersham, Cheryl Gillan, has announced that she will take forward an Autism Bill in the UK Parliament, with the backing of The National Autistic Society (NAS) and another thirteen autism charities. As the first name out of the private members ballot, any bill that she puts forward should receive sufficient procedural time in Parliament to become law if approved by her fellow MPs.

Her action is a response to what she sees as local authorities' complete failure to meet the needs of the half a million children and adults with autism in the UK, stating that it is "wholly unfair how hard people affected by autism have to fight to get the help they so desperately need. The continuing postcode lottery of autism services across the UK is simply unacceptable and incredibly damaging. Creating the first ever autism law is crucial to helping local authorities take the

necessary action and recognise their responsibilities towards this severely excluded group. Many MPs, cross-party, have already offered their support and I hope many more will back this vitally important bill - it has the potential to radically transform thousands of lives in every constituency and community."

The announcement comes after the NAS 'I Exist' campaign revealed many young people with autism do not receive the kind of support that would help them achieve their potential in adulthood and at least one in three adults with the condition are experiencing serious mental health difficulties as a result. Local authorities have been slow to react; around two thirds of local authorities in England do not know how many children with autism there are in their area and just two are aware of the number of adults with the condition.

The Autism Bill could be the first condition-specific private members' bill to be enshrined in law. Mark Lever, Chief Executive of the NAS, said that the bill is "a huge step forward in ensuring a brighter future for people with this serious, lifelong and disabling condition, but we urgently need support to make this law. Without the right help autism can have a profound and sometimes devastating effect and we will keep campaigning until we see real change at ground level."

The Bill aims to place a duty on local authorities and National Health Services bodies to recognise and fulfil their responsibilities towards people with autism. Measures proposed include: improving local information on the number of children and adults with autism, providing effective support from child to adult services, appropriate staff training, and the promotion of independent living for people with the disability.

More information on autism can be found at <http://www.autism.org.uk>

England: strategy to transform dementia services

Dementia is one of the main causes of disability in later life, ahead of some cancers, cardiovascular disease and stroke. The first National Dementia Strategy in England, backed by £150 million over the first two years, is intended to increase awareness of dementia, ensure early diagnosis and intervention and radically improve the quality of care that people

with the condition receive. The strategy calls for specialist memory services to be established throughout the country. These will allow people with dementia to have their diagnosis made accurately and early in the course of the illness, as well as get access to treatment and intervention that can help them live well with the condition.

Other initiatives recommended in the strategy to help the estimated 570,000 people with dementia in England, as well as their carers and families, include better training for GPs in the recognition of the early symptoms of dementia and access to memory services throughout the country staffed by specialists to provide early diagnosis and treatment. Dementia advisers will be appointed to help people with dementia and their families navigate the care and support system throughout the illness. Access to older people's community mental health teams, which help assess patients in care homes and to help minimise the use of anti-psychotic medication, will be expanded; while actions will be taken to increase access to information on dementia and to help remove the stigma associated with it.

The strategy is recognition that the number of people with dementia will double to 1.4 million in the UK over the next thirty years and the cost of care and treatment is likely to triple to over £50 billion per year. Direct costs of dementia to the NHS are approximately £3.3 billion per year, with overall costs to the UK economy estimated at some £17 billion per year. In launching the strategy Secretary of State for Health, Alan Johnson, stated that "in an ageing society, caring for people with dementia is one of the most important challenges we face. I know that for many people, diagnosis can be difficult, care can be patchy and without adequate support, families can be under huge stress. All that must change."

"The creation of a new role of dementia advisor will be crucial in making sure people and families get the help they need. I also want to see GPs trained to recognise the early symptoms of dementia and be able to refer people with dementia to specialists who can give an effective diagnosis. This will allow people with dementia to get the care and treatment they need and remain as independent as possible for as long as possible. We owe them, their carers and their families nothing less."

Chief Executive of the Alzheimer's Society, Neil Hunt, welcomed the announcement calling it a "momentous opportunity to avert a dementia crisis that could overwhelm the NHS and social care". Also welcoming the launch of the Strategy, Maurice O'Connell, Chairman of Alzheimer Europe, said, that he was delighted "that this long-awaited strategy will now be implemented and that England joins Norway, France and Scotland in giving dementia the priority it deserves. I hope that other national European policy-makers take heed and implement their own national dementia strategies."

The Dementia Strategy can be found at <http://www.db.gov.uk/dementia>

Ireland: HSE progress in tackling MRSA in hospitals

The rate of MRSA in hospitals nationwide has fallen according to a Health Protection Surveillance Centre (HPSC) report published on the 29 January, suggesting that the Health Service Executive is on track to meet a five-year target for reducing MRSA rates set in 2007.

The figures relate to *Staphylococcus aureus* (S. aureus) blood stream infections for acute public hospitals in Ireland. While some patients come into hospital with S. aureus blood stream infections, many cases are health care associated infections (HCAI). Some of these infections are antibiotic resistant, so called MRSA (methicillin resistant *Staphylococcus aureus*), and can be more difficult to treat so patients need to be managed to prevent cross infection.

Key findings in the report indicate that MRSA rates have fallen by 25% from 2006 to the latter half of 2008. This is the second consecutive report from the HPSC showing a reduction in MRSA rates. If this rate of progress is maintained, the HSE could achieve a 30% reduction in MRSA ahead of its five year target. Annually, trends have been downwards from 575 MRSA cases in 2006 to 430 again towards the final half of 2008. The total number of S. aureus bloodstream infections has also decreased since 2006.

The reduction of HCAI is a key priority for the HSE. HCAI, including MRSA, is a challenge for all health systems as health care becomes more intensive, complex and invasive. Welcoming the report HSE Chief Executive Brendan Drumm said that while there is no room for compla-

ncy where hospital infection is concerned, today's report showing a reduction in the rate of MRSA in HSE hospitals confirms that we are making real progress in tackling this important challenge."

Ireland: HIQA report on hospital hygiene

The Health Information and Quality Authority in Ireland launched its second National Hygiene Services Quality Review on 22 December. The review assessed fifty acute care hospitals against the National Quality Hygiene Standards and provides patients, the public and staff with detailed information on the hygiene services in each of these hospitals and the overall national picture of the quality of hygiene services across the country.

The review reflects a snapshot in time and demonstrates that, overall, there has been an improvement in the quality of hygiene services as compared to the previous year, with a number of areas identified as having improved. These include a multi-disciplinary approach to hygiene services, the structure of hygiene services in hospitals, the management of linen, hand hygiene and the management of waste.

However, a number of areas are identified that require further improvement. These include the evaluation of data and information, the monitoring of staff satisfaction, health and wellbeing, reporting timely and accurate data and information, the development and maintenance of guidelines for staff and the evaluation of the performance of hygiene services staff.

In comparison with the hygiene performance in last year's review, the 2008 results show that there were nearly twice as many 'A' ratings, the highest level of compliance against the standards, awarded across the hospitals this year. An increase in 'B' ratings was also seen together with an associated decrease in 'C' ratings.

"The improvement in the ratings of some hospitals is acknowledged and welcomed. However, a number of hospitals maintained the same level of performance and, in some, their performance has deteriorated. Hospitals which scored poorly in core hygiene delivery criteria saw their overall rating drop. These hospitals must work more effectively to manage the necessary improvements in their hygiene services and the safety of the care they provide to patients" said Dr Tracey

Cooper, Chief Executive of the Health Information and Quality Authority.

“The Authority believes that, where poor standards of hygiene exist in our hospitals, this should not be tolerated. We need to continue to move towards a culture of ‘zero tolerance’ in relation to healthcare associated infections. Strong leadership and management in this area are vital in order to ensure that high quality standards in hygiene services are optimum, effective and embedded 24 hours a day, seven days a week.”

The Minister for Health and Children, Mary Harney welcomed the report but noted that not all hospitals had improved and that there was still too wide a gap between those doing well and the under performers stating that the department was considering “further targeted initiatives early in the new year to ensure that the measurable improvements achieved in 2008 are further built upon in 2009. The aim is that the high standards that have now been achieved in some hospitals must be replicated right across the service.”

The HIQA report is available at http://www.hiqa.ie/media/pdfs/hygiene/2008/National_hygiene_report_2008.pdf

Germany: Ulla Schmidt warns of health insurance cash crunch

Germany’s public health care system could come up short of cash in 2009. If the economy declines, the new universal premium set by the government might not be enough, Health Minister Ulla Schmidt said in an interview with the German public broadcaster ZDF on 28 December.

Minister Schmidt said that she could not say for certain if the government’s new common health premium, currently set at 15.5% of the insured’s gross pay, would stay at that rate next year. These doubts over the financing of the German statutory health care system were made public just days before reforms to the health system came into effect.

If the German economy shrinks by 2% in 2009, as many economists are predicting, this would lead to a loss of €440 million for the government’s new so-called health fund, the pool of money from which the insurers in the future will receive a basic sum to cover their customers. If the 15.5% premium rate leads to financing shortfalls at health insurers, they would have to ask their members to make up the difference. The government will first

decide next autumn if the common health premium should be raised, Schmidt said.

The universal health premium is part of a broader health care reform package by the government. The amount of money each insurer receives from the health fund will now depend on its members. Those insurers with more chronically ill people, for example, will get more money. The reform will take contributions from a current average of 14.9% of gross pay to 15.5%. Health insurance contributions are generally borne roughly equally by salaried workers and their employers in Germany.

In the interview Schmidt pointed out that one of the elements of a second economic stimulus plan under discussion was a tax subsidy for the new health fund. This plan, has subsequently been endorsed by the Cabinet in January 2009. If approved by Parliament this will reduce insurance premiums from 15.5% back to 14.9% by the middle of the year.

However Herbert Reichelt, the incoming head of Germany’s biggest public insurer AOK, said he does not believe that the 15.5% rate will be high enough for all of Germany’s public insurers. He predicts a shortfall of between €700 million and €1 billion. While his company, AOK, will stay above water with the 15.5% premium rate, he believes others will likely have to ask their members to make additional contributions.

Russia tightens disease control amid bird flu deaths in China

In Moscow on 28 January Russia’s Chief Medical Officer, Gennady Onishchenko, instructed regional authorities to tighten disease control measures amid a rise in the number of bird flu cases in China. According to the World Health Organization, eight cases of human bird flu infection have been registered worldwide in 2009 – two in Egypt and six in China, where five people have died. However, the WHO said they did not believe China was facing a bird flu epidemic as all the cases were scattered around the country and appear to be random.

A press statement from his office states that he has instructed that quarantine stations at crossings on the Chinese border be provided with disinfectants, individual protective clothing and equipment to identify people with increased body temperature arriving from China and other countries of bird flu

concern. Onishchenko also urged improved measures of bird flu vaccinations for people working at poultry farms. Disease control will also be tightened at markets selling live poultry and pet birds, as well as at airports receiving flights from China and other bird flu-affected countries.

A total of 399 cases of human infection with the deadly H5N1 strain of bird flu have been registered worldwide since 2003, in 252 of them have been fatal. No confirmed cases of human bird flu infection have been reported in Russia, although some cases have been seen in domestic poultry in recent years. In the past the Russian authorities have been quick to act, culling thousands of birds, placing affected areas under quarantine, and imposing tight controls on battery farms that supply Moscow with chicken and eggs.

Netherlands: Drugs advisory committee established

The Dutch Ministry of Health, Welfare and Sport announced on 23 January that a committee of experts will advise the government on whether Dutch drug policy should be modified and, if so, on the best way of achieving this. Their advisory report will be incorporated into the new memorandum on drugs.

The country’s present drug policy is currently the subject of an assessment study. The advisory committee will take stock of the results of this study, and will present its report no later than 1 July, 2009. The government will present the drugs memorandum before the end of the summer recess.

In addition to public health and safety, the government has asked the advisory committee to address the social and community aspects of this issue, such as school drop-outs. The committee will also look into the question of whether the status of certain drugs on the two lists of the Opium Act should be re-examined. List I is for hard drugs, list II for soft drugs. Other areas of investigation include: ways of improving prevention and care in the case of addiction; future options for coffee-shop (establishments that are licensed to sell small quantities of cannabis to adults aged over eighteen) policy; and what action is needed to reduce the Netherlands’ involvement in the production, transit, and distribution of XTC, cannabis and cocaine.

News in Brief

Long-term perspective needed to face impact of financial crisis

The health sector needs to take urgent steps to counter the negative consequences of the financial crisis on global health. But countries also need to take a long-term perspective so their health systems are more resilient in the future, said participants in a high-level consultation held at the World Health Organization, Geneva, on 19 January. They suggested five areas of action for WHO and policy-makers: leadership, monitoring and analysis, pro-poor and pro-health public spending, policies for the health sector based on primary health care, and new ways of doing business in international health.

More information at http://www.who.int/mediacentre/events/meetings/2009_financial_crisis_report_en_.pdf

Northern Ireland: Prescription charges reduced from January 2009

Prescriptions will cost only £3 per (rather than £7.10 per item) from 1 January 2009. The reduction in charges will last until April 2010, when free prescriptions for everyone will be introduced in Northern Ireland. In Wales, prescription charges were abolished in April 2007, while the Scottish Executive has decided to introduce a phased abolition of prescription charges so that by 2011, there will be no charges for prescriptions.

England: Prescription charges abolished for cancer patients

The English Department of Health has also announced that it will abolish prescription charges for cancer patients in 2009. Up to 150,000 patients already diagnosed with cancer are expected to benefit, and may save £100 each year in prescription charges. The changes come into effect from 1 April. Prime Minister Gordon Brown has also announced that in future other patients with long-term conditions will also receive free prescriptions. Professor Ian Gilmore, President of the Royal College of Physicians is undertaking a review of prescription charges for people with long-term conditions that will report to Ministers in summer 2009.

More information at <http://www.dh.gov.uk/prescriptionchargesreview>

eHealth High Level Conference

A Ministerial Conference 'eHealth for Individuals, Society and Economy' is taking place in Prague on 18–20 February 2009 under the auspices of the Czech Presidency. It is focusing mainly on the impacts of eHealth solutions and processes rather than on their technological background, although advanced and accessible information and communication technology is an essential element of all eHealth concepts.

The programme and other documentation are available at <http://www.ehealth2009.cz>

Finland: National Institute of Health and Welfare Launched

The National Institute for Health and Welfare came into being on 1 January 2009 following a merger of the National Public Health Institute and the National Research and Development Centre for Welfare and Health (STAKES). It will undertake a range of research and development, provide guidance and maintain a number of national services, including infectious diseases monitoring and acting as the statutory statistics authority for health and welfare. The new Institute will maintain and promote close contacts with EU bodies, the WHO and a number of scientific and public institutions and agencies, as well as affiliate organisations around the world.

More information at http://www.thl.fi/fi_FI/web/fi

Newly reported HIV cases on the rise in Europe

A joint report from the European Centre for Disease Prevention and Control (ECDC) and the WHO Regional Office for Europe illustrates that the HIV epidemic remains a major public health issue, with evidence of increasing transmission of HIV in several countries. Case reporting data from 2007 show that the number of newly reported cases in the WHO European Region continues to rise. Between 2000 and 2007, the annual rate of HIV infection almost doubled, from 39 to 75 per million population. The highest reported HIV rates were in Estonia, Ukraine, Portugal and the Republic of Moldova. In the forty-four countries that have consistently provided data since 2000, the annual

number of newly diagnosed cases increased from 21,787 to 41,949.

In addition to the surveillance report, detailed data and an analysis of the HIV/AIDS situation in each Member State are available on both the WHO Regional Office website www.euro.who.int/aids and the ECDC website www.ecdc.europa.eu

Commission launches consultation on the future of Europe's health workforce

On 15 December the European Commission adopted a Green Paper on the EU Workforce for Health. It marks the beginning of a consultation period that aims to identify common responses to the many challenges facing a health workforce that accounts for about 10% of all jobs in the EU. Many of these challenges are common to all Member States. The ageing population is changing the pattern of disease and placing new and increasing demands on health care workers. It also means that the health workforce is itself ageing, while there are insufficient new recruits to replace those that are retiring or leaving the EU. Migration of health professionals into and out of the EU and mobility within the EU also has impacts on the supply and distribution of health workers.

Important issues raised in the Green Paper include investing in training and developing robust human resource strategies to improve recruitment and retention. One such area is, for example, improving the status and participation of women in the health workforce. The Green Paper also raises the importance of balancing how we address shortages within the EU with broader global healthcare considerations.

Responses to the consultation should be received by 31 March 2009. The Green Paper is available at http://ec.europa.eu/health/ph_systems/workforce_en.htm

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